

THE REGULATION OF
MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS
A COMPARATIVE STUDY

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*To My Family
and MC*

This is to declare that the thesis has been composed only by my Work.

Miriam Aziz

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PREFACE

This thesis derives from an interest which has matured since my final year as an undergraduate at the Faculty of Law, University of Manchester. In particular, I refer to the "Law, Medicine and Ethics" course which provided me with an invaluable framework in which to develop my interest in medical jurisprudence. Professor Margaret Brazier delivered a lecture on medical research at the end of the Spring term (1992) which she drew to a close by stating that, "Seeing as questions of medical research affect society, they should also be resolved by society". I did not know then that these words were to form the basis of my thesis. Over the Easter holidays, I came across the transcripts of the Nuremberg trial at the law library of the Free University of Brussels and I soon began to ask myself the question which is one of the staples for medical research involving human subjects: how could doctors commit such terrible atrocities? Moreover, how could society allow these terrible things to occur? How were the safeguards overridden? Was the phenomenon of unethical research delimited by geography, namely, was it solely a German phenomenon?

This thesis is designed around the comparative method for several reasons. Generally, the intellectual challenge of forming an understanding of a different legal system is an end in itself to the extent that it promotes the pursuit of ideas.¹ Moreover, it fosters a greater understanding of the domestic legal system which can be viewed in a wider perspective. Ultimately, however, comparative method serves a practical function. The current position in the United Kingdom is that the application of official controls as regards medical research has been unsystematic and haphazard. Research in Germany, on the other hand, is severely regulated by the Drugs Code (*Arzneimittelgesetz - AMG*).²

¹"...by the international exchanges which it requires, comparative law procures the gradual approximation of viewpoints, the abandonment of deadly complacency, and the relaxation of fixed dogma. It affords us a glimpse into the form and formation of legal institutions which develop in parallel, possibly in accordance with laws yet to be determined, and permits us to catch sight, through the differences in detail, of the grand similarities and so to deepen our belief in the existence of a unitary sense of justice." Zweigert, K and Kötz, H *Introduction to Comparative Law* (2nd rev. edn, 1992, Weir, T (tr)) at p. 3.

²Historical references to Germany are confined to the Federal Republic of Germany prior to Unification because of the difficulty in obtaining access to materials as regards unethical research

References will also be made to the United States given the advanced development of the regulation of medical research in that country. The outlook of this work, however, is inherently European as opposed to Anglo - American. This has less to do with what some have defined as the “gradual convergence”³ or the “vanishing distinction”⁴ between the common and the civil law systems and more to do with the fact that both the United Kingdom and Germany are part of the European Union. In effect, both England and Scotland have ceased to be a “legal island” and have joined the mainstream of the European legal tradition.⁵ Much can be learned by setting aside national barriers; this calls for co - operation which goes beyond comity. It is submitted that a degree of harmonisation of the regulatory measures for medical research is required across the Union. This would avoid the possibility of pharmaceutical companies indulging in “forum shopping” for places to conduct their research. The United Kingdom should not become the sweat shop of the pharmaceutical industry. Thus, both systems will be viewed as presenting national variations of a common theme, the regulation of medical research involving human subjects.

The British reader will be familiar with the background to the law in the United Kingdom but will probably be less at ease with the German legal system. I have therefore provided an outline of German law in Appendix A.

As part of my research, I sent out questionnaires to research ethics committees in Scotland. a summary of the results are annexed in Appendix E. I would particularly like to thank Mr Sheldon, former chairman of the Tayside Committee on Medical Ethics

practices in the former German Democratic Republic. Details concerning the GDR’s past are now beginning to emerge. See Glees, A and Rose, D in *The Observer*, August 12, 1997 at pp. 1-3.

³Markesinis, B M *The Gradual Convergence: Foreign Influences and English Law on the Eve of the 21st Century* (1994) and also Markesinis, B M ‘Judge, Jurist and the Study and Use of Foreign Law’ (1993) 109 LQR 622. *Contra* Legrand, P ‘European Legal Systems are not converging’ (1996) 45 ICLQ 52.

⁴Gordley, J ‘Common law and civil law: eine überholte Unterscheidung’ (1993) 1 ZEuP 498.

⁵Sir Thomas Bingham in FA Mann lecture ‘There is a World Elsewhere’ (1992) 41 ICLQ 514, Zimmerman, R ‘Savigny’s Legacy. European Legal Science’ (1996) 112 LQR 576 and also Birks, P ‘Adjudication and Interpretation in the Common Law: a Century of Change’ (1994) 14 LS 156 and also Edwards, D ‘The Scottish Reaction - An Epilogue’ in Markesinis (1994), fn 3 above at 263.

in Dundee, and Mr Moore, acting medical adviser to the said committee who both provided me with invaluable insights into the practices of research ethics committees. I would also like to thank the members of the Central Manchester Research Ethics Committee who allowed me to sit in on one of their meetings in March, 1995.

This thesis would not have materialised had it not been for the support and encouragement of certain people.

A special thanks goes to my family - my parents, in particular, who kept their faith despite their worries that their daughter had become eine *ewige Studentin*.

I thank my supervisor Professor J K Mason for his undying patience and support towards a supervisee who, at times, tried to throw her arms around the world (including Pontius Pilate!) in trying to write the thesis. His role *in loco parentis* was much appreciated especially when his supervisee's nerves were frayed - during prolapses and otherwise.

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The staff at the law library at the University of Edinburgh deserve many medals as do the staff at the *Staatsbibliothek zu Berlin (Preußischer Kulturbesitz)* and the law library of the Free University of Berlin who showed extreme indulgence towards a researcher whose grasp of library etiquette was perhaps not as correct as it could have been. I am grateful to the *British Federation of Women Graduates* for their financial support and

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Last but not at all least, I thank Matthias Mahlmann whose love, encouragement and assistance have helped sustain the onslaught on hurdles - disc shaped and otherwise - and has added to the reserves needed to face what have sometimes been proved to be overwhelming questions.

The law is stated at August 1, 1997.

Edinburgh,

September 1, 1997

MA

Author's note: This thesis follows the Interpretation Act 1978, s 6 in that, unless the contrary intention appears, words importing the masculine gender include the feminine and words importing the feminine gender include the masculine.

ABSTRACT

This thesis is concerned with finding an appropriate legal response to medical research involving human subjects. The history of the regulation of medical research testifies to the social climate within which research has been conducted. This includes the evolution of the doctor as scientist which led to the objectification of human beings as research subjects, the presence of ideologies in times of war, for instance, which took hold of national consciousness and conscience thereby shifting the goal posts of justification, and the development and nurturing of medical careers.

The first section contains Chapter One which consists of an historical account of forms of unethical research and asks two questions. First, how could such things have been done in the name of research? Secondly, how could society allow them to take place? How were the safeguards overridden? What was the environment or climate within which unethical research was allowed to flourish? Chapters Two, Three and Four comprise section two and deal with the intellectualisation of questions of research at the abstract level of the medico / legal debate. In particular, Chapter Two outlines the terminology of medical research, the monopoly over which has been secured by scientists through scientific discourse. Chapter Three considers the legal discourse in relation to the concept of informed consent and considers the implications of an approach based on medical negligence, in itself a retrospective 'after the fact' approach; it will be argued that medical research should be viewed prospectively within a framework which is more informed by public than private law. Chapter Four considers the role of moral discourse in relation to its main protagonists, 'bioethicists', who retain a firm grip on the ethical implications of medical research. An alternative rationale will be suggested which is both universally applicable and normatively neutral. It will be further argued that moral discourse should involve the public sphere and should not be confined to the private realms consisting of the educated intuitions of researchers and other members of the professional élite.

The third section consists of Chapters Five and Six and are concerned with the research debate as seen in research ethics committees in both the United Kingdom and Germany. In particular, I consider the overall lack of accountability of research ethics committees with reference to the application of judicial review and some of its shortcomings when applied to the decisions of research ethics committees. I examine, for example, the lack of procedural uniformity of the practices of committees, the difficulty in invoking a remedy in view of the predominantly oral nature of the proceedings, the restrictive limitation period on judicial review in England and Scotland and so on. These are difficulties, which as I shall argue, could be curtailed by the introduction of a Statute for medical research. Chapter Seven considers this issue and others raised in the thesis in the shape of proposals for reform which include inter alia a suggestion for an act of parliament which places the medical research process on a democratic, participatory and transparent footing. Procedures will be discussed which enables the research debate to be egalitarian at both an abstract and applied level and which minimises the democratic deficit. Medical research is the responsibility of society; this responsibility can not continue to be demitted to committees which despite being a necessary element of the regulation of medical research, should not be used to 'duck the issue'.

INTRODUCTION

'Experimentation' is defined as a pragmatic alternative to accepted treatment. 'Medical research' by contrast, involves a preordained protocol or plan from which a researcher cannot deviate. Both involve participants or research subjects. It is, however, the latter which is the subject of this thesis.

The search for an increased understanding of the human body and the way in which it is affected by disease is a dynamic process; it also illustrates the power of knowledge. The greater the knowledge, the greater the understanding of how the fight against disease can, in some cases, be contained, and in others, be won. To this extent, the history of human experimentation is as old as medicine itself for research plays a vital role in the development of medicine.

The quest for a higher standard of care is relentless. Doctors want to give their patients the best available treatment.¹ A doctor's duty, as enshrined in the Hippocratic Oath, is to prescribe treatment which is for the good of his patient, albeit according to his ability and judgement. Moreover, he must never do harm to anyone.² The human body can be unpredictable despite its dependence on the laws of nature. This is amplified in its response to illness. Each individual treatment may involve a degree of experimentation.

Medical research alters the doctor / patient equation considerably. There is, in fact, no such relationship in the case of non-therapeutic research. In both therapeutic and non-

¹"Nowhere is the melioristic goal more inherent than in medicine. To the physician, it is not gratuitous. He is committed to curing and thus to improving the power to cure." Jonas H 'Philosophical Reflections on Experimenting with Human Subjects' in Beauchamp, T L and Walters, L *Contemporary Issues in Bioethics* (2nd edn, 1982) at p. 527.

²See the Hippocratic Oath as reproduced at p. 429 of Mason, J K and McCall-Smith, R A *Law and Medical Ethics* (4th edn, 1994) and further in Beauchamp, T L and Childress, T F *Principles of Biomedical Ethics* (3rd edn, 1990) for its modern crystallized form.

therapeutic research, however, the health carer becomes a health researcher and the patient or volunteer moves from the position of a subject to that of an object. Research involving human subjects may expose the individual to the possibility of harm without, at the same time, offering him any benefit. The interests of the patient may be measured against the possible benefit to society as a whole. The medical therapeutic researcher is wielding a double edged sword in fighting for the good of his patient at the same time as satisfying his duty towards society.

THE MEDICAL RESEARCH CONTEXT

Medical research must not be viewed according to the treatment model given that different interests are at stake, such as those of science and scientists, of the community, of the financiers of research, and those of the researched upon. The presence of these interests give rise to social dynamics which are absent from the treatment model. The research process is inherently political.³ Thus, a contextual distinction between ordinary treatment and research must be drawn. Medical research will be analysed in this thesis in the light of the political - ethical challenges that it poses, which some have referred to as 'Biopolitics'.⁴

THE CONCEPT OF RISK

When deciding how to treat his patient, a doctor bears in mind the risks which ordinarily attach themselves to any type of medical intervention ranging from prescribing analgesics to cardiac surgery. We are living in what Beck has termed the 'risk society'.⁵ We incur risks on a daily basis. Every time we cross a road or get into a car we risk serious injury or even death. Yet risks of this type have come to be accepted as part of everyday life.

³McNeil, P *The Ethics and Politics of Human Experimentation* (1993).

⁴Heller, A and Riekman, P (eds) *Biopolitics. The Politics of the Body, Race and Nature* (1994).

⁵Cf Beck, U *The Risk Society: Towards a New Modernity* (1992, Ritter, M (tr)).

In the risk society, however, *everyone* is at risk.⁶ Thus, the *response* to risk must be democratically based.

The responsibility for supervising research has traditionally been delegated to those dedicated to the supervision of others, an intellectual *élite*.⁷ The present position reflects and reinforces the existing social stratification.⁸ A consequence of *élitism* is that it restricts the involvement of members of the community in deciding what sort of research may be carried out.

THE INFLUENCE OF THE PROFESSIONAL ÉLITE

Membership of the *élite* implies the attainment of a position of superiority within society by virtue of qualities and qualifications of distinction. The inevitable consequence is that the *élite* tend to be inward looking.⁹

The medical research debate provokes competition between different schools of professional thought, in particular those of scientists, lawyers and moral philosophers or bioethicists. An appropriate ethical and political response to medical research necessitates defining the role of these participants who should not monopolise the debate which should also be both informed by and open to the general public.

This is particularly important when applied to the research ethics committee which remains the main model for accountability as regards research. Currently, members of

⁶Beck, fn 5 above at 36-38.

⁷"Risks are defined as the probabilities of physical harm due to given technological or other processes. Hence technical experts are given pole position to define agendas and impose bounding premises *a priori* on risk discourse." Beck, fn 5 above at 4.

⁸Cf Putnam, R D *The Comparative Study of Political Elites* (1976) at p. 3.

⁹"Individuals are not intellectually, morally or physically equal, and society is not homogenous. On the contrary, it is composed of vastly numerous social groups, mixing in innumerable ways. In any particular grouping, some people are more capable than others. Those who are most capable in their peculiar branch of activity, whether this be playing chess or playing the prostitute, thieving or defending thieves in the law courts, writing poetry or governing the country, are *le classe elette*, the 'select' persons of their particular grouping: in the French tongue, *l'élite*." Pareto, V in Finer, S E (ed) *Sociological Writings* (1966, Mirfin D, (tr)) at p. 51.

committees are still chosen from professions giving it an outlook which is inherently middle class. I do not propose to be anti-élitist in this thesis. I will, however, canvass the opinion that the medical research process should be structured in such a way as to allow all those affected to participate in resolving the issues that it raises, while, at the same time, leaving some issues for specialised and expert treatment.¹⁰

I have sought to distance myself from the traditional medico / legal approach in view of the dominance therein of the fault doctrine, which is a retrospective method of devising principles. The medical research process should be controlled prospectively and requires a different approach. Public opinion is sensitive to procedures involving aborted foetuses, children and the like which should be controlled before they are undertaken taking into account the views of all those who are likely to be affected. Thus, the medical research process should involve a greater degree of participatory democracy in order that questions of research can be resolved by society in the widest sense of the word.

THE MEDICAL RESEARCH PROCESS; ALTERNATIVE MODELS

In the search for a prospective formula, the existing regulatory framework has much to offer and should certainly not be dismantled. Nonetheless, current thinking is haphazard and undemocratic;¹¹ what is required is a refinement of the *status quo*. One such model is provided in Germany where medical research is closely regulated. The German Drugs Code (AMG)¹² is not as strict as its regulatory nature implies. It is, for example, far more pragmatic than is the regulation of animal experimentation¹³ or of embryo research.¹⁴ However, in contrast to the United Kingdom, there is a blanket ban as

¹⁰Cf Habermas, J *Between Facts and Norms: Contributions to a Discourse Theory of Law and Democracy* (1996) at p. 359-360.

¹¹I shall approach this issue by means of a debate of the theories of Jürgen Habermas, particularly in relation to his most recent work, fn 10 above, Ulrich Beck and Neil MacCormick who allow us to see how societal responsibility can be realised.

¹²Arzneimittelgesetz of 19. 10. 1994 BGBl. I, 3018 at 3040.

¹³See the Tierschutzgesetz of 18. 8. 1986 BGBl. I, 1319.

¹⁴Embryonenschutzgesetz of 13. 12. 1990, BGBl. I, 2746. For an overview see Riedel, E 'The Constitution and Scientific and Technical Progress' in Starck, R (ed) *New Challenges to the German Basic Law* (1991) at p. 61 et seq.

regards embryo research in Germany.¹⁵ This is a product of the backlash which resulted from the atrocities committed during the second World War in German concentration camps. The collective guilt which this engendered still forms part of the national consciousness.¹⁶ The advantage of the German position is that it provides a regulatory framework within which the principles to be applied are spelled out. As we shall see in the chapter dealing with research ethics committees, however, the German model is also inherently élitist.

Other models of decision-making will be suggested which are considered to be more egalitarian and which allow for increased participation within a constitutionalised framework. In addition, one has to consider possible parallel contributions to the debate by, for example, Citizens' Juries. The regulation of medical research is a matter of responsibility and not of fault.

¹⁵See the Human Fertilisation and Embryology Act 1990.

¹⁶See Riedel, fn 14 above at 65.

SECTION ONE: CONTEXT

CHAPTER ONE

THE HISTORY OF THE REGULATION OF MEDICAL RESEARCH

*" 'The purest experiment in treatment may still be conscientious: my business is to take care of life, and to do the best I can think of for it. Science is properly more scrupulous than dogma. Dogma gives charter to mistake, but the very breath of science is a contest with mistake and must keep the conscience alive.' Alas ! the scientific conscience had got into the debasing company of money obligation and selfish respects'
Is there a medical man of them all in Middlemarch who would question himself as I do?' said poor Lydgate."*

George Eliot ¹

1.1. THE INCREASING IMPORTANCE OF RESEARCH

There can be no doubt that the research explosion which ensued at the first half of the twentieth century, and which was catalyzed by both World Wars, was a direct consequence of an earlier move to improve research methods.² The end of the 19th century and the early 1900s bore witness to the quest to legitimate medical hypotheses by deploying the methodology of the natural sciences. Medical schools encouraged their students to think like scientists. The superiority of objective experimentation was formally recognised, primarily through Claude Bernard, whose teachings lay at the centre of this evolution in medical thought.³ The application of physiological and biochemical experiments to the individual was gradually accepted. A new breed of practitioner began to emerge - the scientific physician or, as he now would be described, the medical researcher.⁴

¹Eliot, G *Middlemarch*, Harvey, W J (ed) (1985) at p. 795.

²The main sources for this section are Castiglioni, A *A History of Medicine* (2nd edn, 1947, Krunghaar, E B (ed) (tr)) and Dow, D D (ed) *The Influence of Scottish Medicine* (1988).

³Cf Bernard, C *An Introduction to the Study of Experimental Medicine* (1957, Green, H C (tr)).

⁴See Castiglioni, fn 2 above at 763.

The practice of medical research had at long last found its way to the laboratory, away from the clinic and away from the bedside. This shift in emphasis was in direct contrast to the Boerhaavian tradition which held that the patient ought to be at the centre of medical attention.⁵ The 'new scientists', however, adopted a different position. How was medicine to advance if, as Boerhaave maintained, theoretical discussion was out of place at the patient's bedside? Placing the centre of research in the laboratory meant that theories could be devised and tested through observation. Patients could then be treated according to principles which had been tested and proved.

1.1.1. INTERNAL MEDICINE

The scientific clinician in the nineteenth century was essentially a pathologist. This was particularly apparent in Germany, where a period of great economic prosperity ensured the development of some exceptionally fine laboratories. Every hospital clinic was equipped to carry out intricate investigations. The great German clinicians of the time excelled, more often than not, in both pathology and bacteriology. German universities prided themselves in regarding laboratory studies as being above bedside observations and this trend was to dominate German medicine for years to come.⁶ Even today, it is true to say that before embarking on a scientific research project, a check should be made that it had not been done in Germany before the first World War.⁷

1.1.2. SURGERY

The discoveries of anaesthesia and asepsis, by Simpson and Lister respectively, ensured that surgery did not remain unaffected by the transformation which was taking place. Surgeons, who had hitherto relied on their knowledge of anatomy as a basis for surgical intervention, began to train themselves in pathological anatomy in order to gain a proper

⁵See Castiglioni, fn 2 above at 617.

⁶See Castiglioni, fn 2 above at 829.

⁷See Mason, J K review of Clark, M and Crawford, C (eds) *Legal Medicine in History* (1994) in (1997) 5 Med L Rev 147.

scientific basis for the understanding of disease. Moreover, the progress of operating room techniques as well as the pressure to undertake increasingly severe ablative operations contributed to the birth of a new era in surgery.

There was, however, resistance to this approach which derived from the tension between the old learning and the new; in other words, walking the wards versus scientific experiment.⁸ Thus, many surgeons sought to undermine the novel techniques and the 'new fangled' inventions. Despite this, the race to be at the forefront of medical progress was on right across the globe. Medical education had to adapt itself to this new dimension. Accordingly, great reforms were set to sweep not only across central Europe but also throughout the United Kingdom and the United States.

1.1.3. MEDICAL EDUCATION

1.1.3.1. THE UNITED KINGDOM

The United Kingdom's response was to some extent shackled by its emphasis on clinical instruction. Students gained early admission to the wards but received little instruction in laboratory work, which deprived them of the insight into the way in which a greater understanding of disease could be gained by research. Indeed, at the University of Edinburgh, then regarded as one of the best undergraduate courses in the world, the only laboratory training which students received consisted of testing urine for sugar.

In 1868, a letter appeared in the British Medical Journal by Syme, a distinguished physician of the time, who wrote that medical education was,

“...a preparation...merely for passing examinations which, for the most part, imply neither an accurate knowledge of facts nor the possession of sound principles, being simply affairs of memory loaded with dry terminology.”⁹

⁸Youngson, A *The Scientific Revolution in Victorian Medicine* (1979) at p. 16.

⁹(1868) i BMJ 371.

George Eliot addresses this point in her novel *Middlemarch* which is set during the latter part of the nineteenth century. In the book, the majority of physicians do not question themselves in the way that Lydgate does because they were not trained to do so. Lydgate retires to the country in order to pursue a lifelong interest in research, having completed part of his medical training in France. At first, his methods of treatment are regarded with some suspicion.

As the story unfolds, we begin to see that this is not the common attitude to any newcomer and that Lydgate is quite unlike his fellow practitioners to the extent that he wishes to keep up with the latest in medical thought. He achieves this by dedicating much time to research, uses a stethoscope and advocates the value of post-mortem examinations. This is regarded as highly unusual and he is quietly undermined by his colleagues.¹⁰

The medical community was then, as it is now, a small community, operating according to a closed, village - like mentality. The acceptability of ideas depended on a physician's personality.¹¹ Lydgate's slightly abstract and remote nature helps to reinforce the way in which he is mistrusted. In the end, he is defeated by the conservatism which is so ingrained in the medical establishment of the time.

¹⁰“Lydgate has lots of ideas, quite new, about ventilation and diet, that sort of thing,” resumed Mr Brooke, after he had handed out Lady Chettam, and had returned to be civil to a group of Middlemarchers.

“Hang it, do you think that is quite sound ? - upsetting the old treatment, which had made Englishmen what they are” said Mr Standish.

“Medical Knowledge is at a low ebb among us,” said Mr Bulstrode, who spoke in a subdued tone, and had rather a sickly air. “I, for my part, hail the advent of Mr Lydgate. I hope to find good reason for confiding the new hospital to his management.”

“That is all very fine,” replied Mr Standish, who was not fond of Mr Bulstrode; “if you like him to try experiments on your hospital patients, and kill a few people for charity, I have no objection. But I am not going to hand out money out of my purse to have experiments tried on me. I like treatment that has been tested a little.”

“Well, you know Standish, every dose you take is an experiment - an experiment, you know,” said Mr Brooke, nodding towards the lawyer.” See Eliot, fn 1 above at 119.

¹¹“Findings are not simply findings; they are the findings of someone. The reputation of the author may affect their credibility; his personality and connections, in a small world, may affect their acceptability.” Youngson, fn 8 above at 219.

Scotland can be distinguished from England to the extent that the need to further medical progress by observing patients and by conducting experiments with new drugs had been recognised.¹² This is because of the nature of the intellectual tradition in Scotland which was, and still is, more broadly based as compared to education in England. As Mason & McCall Smith pointed out in the first edition of *Law and Medical Ethics*,

“The fact that Scotland’s contribution to medicine around that time was disproportionately large in relation to its population may have been due to the wider availability of high quality education in that country.”¹³

However, Scotland also fell behind despite its great contributions to medical progress. Simpson’s discovery of chloroform, for example, was pioneered elsewhere. Lister’s contribution was that of a “solitary entrepreneur in a Scottish System which was sluggish.”¹⁴ Neither men were products of their time for they were both committed scientists who refused to languish in the conservative climate of the Anglophone world. Scientists on the continent, on the other hand, were only too ready to endorse and accept their discoveries.¹⁵

1.1.3.2. GERMANY

The experience in the United Kingdom was in direct contrast to the vitality of continental research and teaching. Medical progress and research teaching in Germany led the world. Medical instruction was made up of lectures and practical work in laboratories and wards. The emphasis was placed on clinical investigation as opposed to clinical observation. Indeed, a professor in Germany was regarded as a lifelong student of his

¹²“If the benefits derivable from physiological science are so limited, from what other and better source is improvement to come? The answer is from accurate observation; in other words enlightened empiricism.” Blane, *G Medical Knowledge* (1819) in Dow, fn 2 above at chapter eight.

¹³At p. 9.

¹⁴See Dow, fn 2 above at 110.

¹⁵“The truth is, that this is a question in science rather than in surgery, and hence, while eagerly adopted by the scientific Germans, and a little grudgingly by the semi-scientific Scotch [sic], the antiseptic doctrine has never been in any degree appreciated or understood by the plodding and practical English surgeon. Happily for his patients, he has for a long time been to a considerable extent practising a partially antiseptic system, thanks to his cleanly English instincts; but it has been like the lady who talked prose without knowing it.” (1878) i *Lancet* 36.

subject as well as a teacher of future practitioners. But it was the United States which was to benefit from the experience in the United Kingdom and Germany. For Germany was but a trustee for a legacy which was finally claimed by the United States, *with interest*.

1.1.3.3. THE UNITED STATES

American medical schools contributed little to medical research during the nineteenth century. This was very much to do with the mood of the time as the United States was more concerned with achieving greater economic growth in a bid to establish itself as a major industrial nation. Consequently, research attracted minimal funding in that it was generally considered too impractical. For example, the funds allocated for medical education in 1891 totalled only \$500,000 as opposed to the sum of \$18,000,000 which was allocated towards study in the well-established discipline of theology.¹⁶

American graduates wishing to keep up with the latest in medical innovation opted to pursue their studies abroad. Until 1820, graduates had tended to favour British and French medical schools. After the Civil War, however, American physicians headed for Germany and Austria. Many returned having acquired a solid foundation in research skills combined with the conviction that the future of medicine lay in the laboratory relying on innovative tools such as the microscope and extolling the virtues of new forms of science, such as bacteriology. In short, they had returned as disciples of the continental pedagogical tradition. It was their influence which helped shape the pattern of things to come.

Great reforms began to be seen in medical education. American universities began to provide better premedical training by combining with the best of foreign methods of instruction within their hospital courses. President Eliot, the then President of Harvard University and a committed scientist, implemented reforms which secured his position in

¹⁶Duffy, J *The Healer; A History of American Medicine* (1979) at p. 229.

the history books as a visionary. By the 1870s, teachers in American medical schools received salaries and by 1892, Harvard medical school had lengthened the course to four obligatory years.¹⁷ As Allbutt put it,

“ this new birth [of medicine] is nothing less than its enlargement from an art of observation and empiricism to an applied science founded upon research; from a craft of tradition and sagacity to an applied science of analysis and law, from a descriptive code of surface phenomena to the discovery of deeper affinities; from a set of rules and axioms of quality to measurements of quantity.”¹⁸

This move was by no means confined to the medical schools. The years spanning 1870 to 1895 saw Harvard Law School virtually transformed under the deanship of Langdell by the introduction of the so-called ‘case’ or ‘Socratic’ method of teaching. Langdell, who had been personally appointed by Eliot, saw the case-method as an inductive reasoning process. The instructor and the student were co-researchers whose aim was to effect the move away from the analysis of a series of concrete cases to the elaboration of general principles of law;¹⁹ law thus became a science governed by logical principles.²⁰ This was very much in tune with the formalist consensus of the time.

The 1890s saw the newly established Johns Hopkins Medical School transformed into a research centre by William H. Welch, who had recently returned from Germany. He was also involved in the promotion of scientific work by medical officers at the Army medical school. By 1900, laboratory training and research were regarded as fundamental to medical education and most medical schools and universities had set up their own research laboratories.

¹⁷Castiglioni cites Oliver Wendell Holmes who wrote of President Eliot that he, “...has turned the whole university over like a flapjack. There never was such a *bouleversement* in the Medical Faculty.” Castiglioni, fn 2 above at 915.

¹⁸Castiglioni, fn 2 above at 915.

¹⁹Chase, A ‘The Birth of the Modern Law School’ (1979) 23 *Amer J Legal Hist* 329 and Duxbury, N *Patterns of American Jurisprudence* (1995) at p. 11 et seq.

²⁰For an illustration of the effect that this had see Oliver Wendell Holmes who firmly believed that jurisprudence ought to include the human element; “The life of the law has not been logic: it has been experience.” Holmes, O W Review of C.C. Langdell, ‘Summary of the Law of Contracts’ (1880) 14 *Am L Rev* 233 at 234.

Nevertheless, the average American physician still retained a degree of scepticism as regards medical research. Indeed, although the practice of blood letting had declined by the end of the nineteenth century, many physicians continued to extol its virtues.²¹ Moreover, the results of research still appeared in scientific journals such as *Scientific American* and *Popular Science Monthly* as opposed to medical journals. Even so, American researchers within the new generation of physicians began to make discoveries of their own despite the stifling training they had received. The scene was set for an explosion of research which was to shake medical science to its foundations.

1.2. THE EXPLOSION OF RESEARCH

The advent of antibiotics catalysed an explosion in the search for synthetic analogues. The effect of each new drug developed could be evaluated only in the medical therapeutic field. Thus, medicine became strongly influenced by the pharmacologists and the age of science-based medicine had begun.²²

1.3. THE CONSEQUENCES

Doctors themselves were not unaffected by this development. They began to objectify their patients, viewing them as subjects to be observed and experimented upon rather than as patients. Was unethical research a direct consequence of this change of balance? To say that this was exclusively so would be over-simplistic and difficult to sustain. It was, however, certainly, a contributory factor. The scientific method which originally led physicians into the laboratory was based on observing primitive organisms such as fruit flies and dog-fish. The distinction which arose from the fact that the research

²¹Fielding H. Garrison writes in 1913 that there is scarcely a physician who "may not suddenly encounter some circumstances in his experience in which venesection would turn out to be his sheet anchor and his patient's salvation." Duffy, fn 16 above at 233.

²²Castiglioni, fn 2 above at 920 - 921.

objects in medical research were predominantly human was never specifically drawn. The scientific method which was adopted by the scientific physicians neither questioned nor was it qualified.

Arguably, this was a foreseeable consequence. However, leaving aside the benefit of hindsight, the possibility of unethical research was not anticipated and was accepted as a phenomenon only when irrefutable evidence of its existence came to light - by which time the horse had already bolted.

It became clear that society had played both a direct and an indirect role in its growth. The responsibility of controlling medical research involving human subjects had been abdicated to the conscience of 'scientific' doctors. The dangers of *laissez faire* were appreciated only after the damage had been done. The anti-rational philosophy of self-expression which formed the basis of Nazism exemplified the dangers of leaving the control of research to the collective conscience of the professional élite.²³ As this next section will show, however, examples of unethical research are not confined to the German physicians of the Second World War.

²³See Wasserman, R 'Zur Wiederkehr des Nürnberger Prozesses gegen die Hauptkriegsverbrecher' (1996) 32 Recht und Politik 34 who cites the twelve concurrent trials to the main Nürnberg trial which began on November 20, 1945 and where the main protagonists of national socialism who were prosecuted were members of the leading professional classes (the doctor's trial, the IG Farben trial (Germany's largest pharmaceutical company), the trial against Südost - Generale, the trials of the central economic and administrative authority of the SS and so on). See also Russell, B *History of Western Philosophy* (2nd edn, 1979) at p. 696 and also Zygmunt Baumann's thesis as outlined in *Modernity and the Holocaust* (1990) where he argues that social norms and institutions made the Holocaust feasible. See p. 87 et seq. See also Healy, M 'The Holocaust. Modernity and the Enlightenment' (1997) 3 Res Publica 35.

1.4. GERMANY

It is commonly assumed that guidelines for research involving human subjects were developed in Germany only after 1945 but the history of the regulation of human experimentation in Germany dates from well before then. Germany, was, in fact, the first country to regulate medical research. We will trace its development through a number of *causes célèbres*.

1.4.1. DR NEISSER AND OTHERS

In 1900 an experiment was conducted by the scientist Albert Neisser, Director of the Dermatological Clinic in Breslau in which healthy prostitutes were infected with syphilis in an attempt to find a preventative cure for syphilis. He injected patients who were admitted for other medical conditions. These patients were not informed about the experiment nor were they asked for their consent. When some of them contracted syphilis, Neisser concluded that the “vaccination” did not work. However, he argued that the women did not contract syphilis as a result of his serum injections but contracted the disease because they worked as prostitutes. Details of the experiment were published by a liberal newspaper which triggered a national outcry.²⁴ Neisser was fined 300,- RM by the Royal Disciplinary Court which held that he should have sought the patient’s consent. The only good to come from it was that it provoked discussion of research involving human subjects.²⁵

Reports began to appear in medical journals exposing more examples of dubious research practices. A year later, yet more revelations appeared in a book which referred to the research subjects mentioned as the “victims of science”. Vikenty Veressayer, a Russian physician, wrote about experiments where cancer had been transplanted and

²⁴Schlaudraff, U ‘Ethics Committees in Germany’ (1992) 80 Bull Med Eth 40.

²⁵See Vollmann, J and Winau, R ‘Informed consent in human experimentation before the Nuremberg code’ (1996) 313 BMJ 1445.

where patients had been exposed to scarlet fever.²⁶ He also dealt with studies on venereal disease in which human subjects had been used because no suitable animal model could be found. He cited an example where a physician who, in attempting to show that a specific micro-organism caused gonorrhoea, inoculated patients without their knowledge in order to show that infection occurred. The infection which ensued was painful and, at the time, incurable.²⁷

The Prussian Government immediately issued a directive to the heads of clinics and similar establishments prohibiting medical intervention for “purposes other than diagnosis, therapy and immunisation” unless certain conditions were fulfilled. Informed consent was needed before such intervention was permissible. Secondly, the use of minors and the mentally incompetent as research subjects was expressly forbidden. The directive also provided that an investigator not only needed to seek approval from the director of a medical institution but that he also had to maintain records which would prove that the provisions of the directive had been observed.

1.4.2. THE LÜBECK CASE

A second major case involved an experiment which was carried out in Lübeck in 1930 where the Calmette-Guerin vaccine was combined with the bacillus of tuberculosis; this culminated in the deaths of 14 children. The Reich government issued detailed “Guidelines for new Therapy and human experimentation” which went into considerable detail. In summary, a distinction was drawn between therapeutic and non-therapeutic research, scientific experiments could not be carried out on vulnerable human subjects, the risk and benefit of each experiment had to be weighed, research subjects had to give their consent and experiments on animals had to be carried out before involving humans.

²⁶Veressayev, V *The Memoirs of a Russian Physician* (1901, Linden, S (tr) reproduced in part in Katz, J *Experimentation with Human Beings* (1972).

²⁷Also see Deutsch, E *Das Recht der Klinischen Forschung am Menschen: Zulassigkeit und Folgen der Versuche am Menschen Dargest. Vergleich zu den Amerikan. Beispiel und die internat. Regelungen* (1979).

However, the protection of research subjects depended on the conscience of physicians. The atrocities committed in the name of medical research during the Second World War and which came to light during the course of the Nuremberg trials indicate that the regulations were ineffective.²⁸ The guidelines of 1931 were not annulled in Nazi Germany.

1.4.3. THE NUREMBERG TRIAL (1947)²⁹

In 1947, twenty three defendants stood trial for their part in the atrocities which took place in concentration camps during the third Reich; all but three of them were doctors. The prosecution was brought by the victorious Allies. The indictment read that each had “participated in a common design or conspiracy to commit and did commit war crimes and crimes against humanity”.³⁰ Details of the acts of barbarity which had been committed under the régime of national socialism emerged as the trial progressed. These details not only shook the conscience of the world but also forced the German people to confront and reconcile themselves with their past.³¹

Details were revealed of the ‘high altitude’ experiments which had been conducted at Dachau for the benefit of the German Air Force to investigate the limits of human physiology. Individuals were exposed to low atmospheric pressure without additional oxygen. Some died as a result whilst others suffered grave cerebral injury. In experiments, referred to during the trial as ‘freezing experiments’, also conducted at Dachau, individuals were forced to remain in tanks of ice water for periods of up to three hours; many died as a result.

²⁸See Deutsch, fn 27 above at 12.

²⁹Note that the trial referred to was one of twelve other trials conducted in conjunction with the main trial which began on November 20, 1945 and which lasted for almost a year. See Wasserman, fn 23 above at 32.

³⁰See Finnie, W ‘War Crimes’ 1990 JR 61 for a useful discussion of the distinction between the charges of war crimes and crimes against humanity.

³¹*Die Zeit* 8 May, 1995.

Other experiments involving infectious diseases such as malaria, epidemic jaundice and typhus as well as those involving poisons and innovative drugs were all listed, transforming the court room into a chamber of horrors. Fifteen out of the twenty three defendants were found guilty. Out of these fifteen defendants, seven were hanged, five were sentenced to life imprisonment, two received a sentence of twenty years and the two remaining were sentenced to fifteen years and ten years imprisonment. Seven defendants were acquitted and subsequently freed.

The judgment in the case *United States v. Karl Brandt*³² provided what later came to be known as the 'Nuremberg Code' which provided the first international declaration regarding research involving human subjects. The first article of the so-called 'ten commandments' dealt with consent;

"The voluntary consent of the human subject is absolutely essential."

Given the context, it is not surprising that emphasis was placed on the subject's consent being voluntary and uncoerced.³³ Later international guidelines have, however, reduced the primacy of the consent requirement.³⁴

A question which was never answered at Nuremberg was this: why was it that doctors so readily engaged in research of this kind ? As was stated in the opening statement made by counsel for the prosecution, Brigadier Telford Taylor,

"...most of them are trained physicians and some of them are distinguished scientists. Yet these defendants, all of whom were fully able to comprehend the nature of their acts, and most of whom were exceptionally qualified to form a moral and professional judgment in this respect, are responsible for wholesale murder and unspeakably cruel tortures."

³²*Trials of War Criminals Before the Nuremberg Military Tribunals. Volumes I and II, The Medical Case.* Washington DC : US Government Printing Office (1948) in Katz, fn 26 above at 292.

³³See Beauchamp, T L and Walters, L *Contemporary Issues in Bioethics* (2nd edn,1982) at p. 506.

³⁴See below.

Indeed, the experimentation was not perceived as an abuse of medicine by its perpetrators and it thus became clear that the proper conduct of research involving human subjects could not be left to the individual conscience of the individual physician.³⁵ However, the practicalities of such a restriction were also acknowledged. As the prosecution expert witness Dr Andrew Ivy said,

“...a state cannot follow a physician around in his daily administration to see that the moral responsibility inherent therein is properly carried out. This moral responsibility that controls or should control the conduct of a physician should be inculcated into the minds of physicians just as moral responsibility of other sorts, and those principles are clearly depicted or enunciated in the oath of Hippocrates with which every physician should be acquainted.”³⁶

Thus, the question as to why doctors committed such atrocities provokes further consideration of the societal climate in which such experiments took place.

1.4.4. DR RASCHER'S CASE

A German physician, Dr Alexander Mitscherlich, was commissioned by the German Doctors Medical Association to cover the Nuremberg trial. The book, *Das Diktat der Menschenverachtung* or the *Dictate of the Contempt for Humanity*³⁷ not only provides an overview of the documentation of the trial, but it also provides an incisive account of the social dynamics and interaction between National Socialism and the medical research community within it.

Mitscherlich, for example, includes the correspondence between a medical researcher, Dr. Sigmund Rascher and Himmler in his book. Rascher had struck up a friendship with Himmler which was not only a meeting of minds but also a type of patronage. Himmler had executive control of the concentration camps. Rascher was a doctor in the

³⁵See generally Katz, J 'Human Sacrifice and Human Experimentation: Reflections at Nuremberg' Yale Law School Occasional Paper (1997).

³⁶Katz, fn 26 above at 300.

³⁷Mitscherlich, A *Das Diktat der Menschenverachtung: Aus der deutschen Ärztekommision beim Amerikanischen Militärgericht I in Nurnberg: Eine Dokumentation vom Prozess gegen 23 SS Ärzte und Wissenschaftler* (1947).

Luftwaffe and an SS-Untersturmführer and was responsible *inter alia* for the hypothermia experiments carried out at Dachau. In the correspondence, he comes across as ambitious, keen and committed. In a letter to Himmler dated 15 May, 1941, for example, he asks Himmler for permission to use people incarcerated in concentration camps as research subjects.³⁸ The letter is a chilling example of how the boundaries between humanity and inhumanity can merge - he begins by thanking him for congratulating him on the birth of his son and adds a request for research subjects whilst confirming at the same time that death will be a certain outcome for the subjects.³⁹ Rascher was not unaware of how his contact with Himmler could further his career. Himmler could provide funds and facilities. He also had virtually unlimited access to raw materials in the form of human beings.⁴⁰ The agreement operated according to the basic principle of supply and demand.

The impression which one gains of Rascher is not only as a careerist. It is clear that he was persuaded by the scientific worth of his hypotheses; thus, the experiments were seen as morally acceptable or justifiable.⁴¹ The research subjects were dismissed as "*rassenschänderische Berufsverbrecher-Juden*" which translates as a shame to the race, professional criminal jews.⁴² The proposals and reports of the observations made are characterised by the anonymity of the research subjects. It is easy to forget that the *Versuchspersonen*, referred to in the letters as 'VP's, are in fact human beings.

"The VPs are placed in the water wearing a full winter and summer pilot's uniform and a pilot's cap."⁴³

³⁸Doc. No. 1606 - PS in Mitscherlich, fn 37 above at 19-20.

³⁹Doc. No. 1582 - PS in Mitscherlich, fn 37 above at 21.

⁴⁰Himmler also, for example, transformed concentration camps such as Sachsenhausen and Buchenwald into depositories and sources of materials needed by the Reich. See Whyte, I B review of Pelt, R J van and Dwork, D *How Auschwitz was built* (1996) in *The Times Literary Supplement* January 31, 1996 at p. 5.

⁴¹"Persönlich würde ich diese Versuche besonders in Kriegszeiten, nicht als unmoralisch betrachten." or "Personally speaking, I would not regard these experiments as immoral, especially during War time." Dr Ruff, director of the Institute for Aerospace Medicine of the German Research Organization for Aviation, Berlin; Doc. No. 473. in Mitscherlich, fn 37 above at 29.

⁴²Mitscherlich, fn 37 above at 32.

⁴³"Die VPn werden mit voller Fliegeruniform, Winter - und Sommer - Kombination und Fliegerhaube bekleidet ins Wasser gebracht."

And further,

“As soon as the cooling down during these experiments reach 28 °, the VP died despite all rescue attempts.”⁴⁴

On the whole, the research subjects are dismissed as anonymous or invisible. To be visible, people have to be aryan as Doc. No. 323 shows where a blonde haired, blue eyed 21 year old woman (“*rein nordisch*”) is about to be used in a cold water experiment (*Aufwärmungsversuchen*). Rascher in fact sees her as a human being and saves her from being used. He even writes of the possibility of her obtaining ethnic rehabilitation through work.

Dr Rascher’s research activities did not go entirely undetected. A certain Dr Wertz, the then director of the Aeronautical Institute in München, tried to have the pressure chamber, where the experiments were being conducted, removed from Dachau. However, the strength of Rascher’s connection to Himmler ensured that this did not occur.⁴⁵ Moreover, despite the fact that there were some physicians who were not convinced of the scientific merit of the Dachau experiments, protests were, on the whole, muted. The letter of Dr Hippke to Himmler, for example, dated 10 October 1942, is not so much of a letter of protest on ethical grounds but of someone who is affected by professional envy.⁴⁶

⁴⁴“Sobald die Unterkühlung bei diesem Versuchen 28 ° erreicht hatte, starb die VP mit Sicherheit trotz aller Versuche zur Rettung.” See a letter from Dr Rascher to Himmler, dated September 10, 1942 Doc. No. 1618 - PS in Mitscherlich, fn 37 above at 38-39.

⁴⁵In a letter to Rascher, Himmler states unequivocally that people who choose to reject the experiments and would thereby rather see brave soldiers die as a result of the hypothermia are traitors to their country; the letter also contains a veiled threat of what might happen to such traitors. “Leute, die heute noch diese Menschenversuche ablehnen, lieber dafür aber tapfere deutsche Soldaten an den Folgen dieser Unterkühlung sterben lassen, sehe ich auch also Hoch- und Landesverräter an, und ich werde mich nicht scheuen, die Namen dieser Herren an den in Frage kommenden Stellen zu nennen.” or “I regard people, who even today reject these human experiments would thereby rather that brave German soldiers die as a result of hypothermia, as traitors to their country and I would not be shy of naming them to the appropriate authorities.” Doc. No. 1609 - PS in Mitscherlich, fn 37 above at 43.

⁴⁶He concedes that the results are encouraging (*ermutigend*) but claims that Rascher omitted to consider certain factors such as cold and goes on to praise the pressure chamber at Tempelhof which

The medical researcher, the doctor as careerist, ambitious, keen and committed as encapsulated by Dr Rascher, by Lydgate, and by Dr Mandel in the *Hyman* case which is discussed below all serve to indicate the importance of viewing the research ambience as a whole rather than as a series of protocols to be evaluated individually.

Reading the transcripts from the trial, it would be easy to assume that unethical research was exclusively a German phenomenon. However, whereas the Germans have been forced to confront their past, the Allies were able to side-step any searching questions about their conduct during the second World War which was not so much as a case of moral and legal immunity as a case of 'selective presentation'.⁴⁷

Nuremberg raised awareness among the German people and introduced the questions concerning the Holocaust as a matter for national consciousness and conscience.⁴⁸ The *Thorotrast* case, for example, which arose in 1961, illustrates the sensitivity which the trials had induced.⁴⁹ The case arose out of a civil claim by a former German serviceman who had sustained severe shrapnel wounds and who was referred to a University clinic. Prior to an operation, the surgeon took an arteriogram of his femoral artery, using the radioactive substance 'Thorotrast'. He took a further arteriogram a few weeks after the operation. The plaintiff later developed cirrhosis of the liver and alleged a breach of duty

was then the new Aviationmedical Research Institute of the Reichluftfahrtministerium which had cooling systems already installed. See Doc. No. 289, dated October 10 1942 in Mitscherlich, fn 37 above at 34. Note that at Nuremberg, Rascher was presumed dead. Dr Weltz was, however, charged but acquitted. The whereabouts of Hippke, who was responsible for the freezing experiments, was unknown.

⁴⁷Telford Taylor, who was part of the American prosecution team, wrote in a subsequent book that it was a mistake to include the Russians on the bench given their role in the atrocities carried out in Finland and Poland in 1939. He cites further examples such as the legality of air raids carried out by the Americans and the British on Germany which are still regarded by many people on both sides as war crimes. See Wasserman, fn 23 above at 34.

⁴⁸See generally Conze, E and Metzler, G *Deutschland nach 1945: Ein Lesebuch zur deutschen Geschichte von 1946 bis zur Gegenwart* (1997) at 248-277. It must be stressed that the German reconciliation with the past is a contested point. See also pp. 249-254 where it is argued that post-War Germany was more preoccupied with regaining economic prosperity than repentance and that blame was seen as belonging exclusively to the National Socialists. See also Röhrich, W 'Die Unfähigkeit zu trauern' at 259 and Werle, G and Wandres, T 'Auschwitz vor Gericht' at 263-267.

⁴⁹BGHZ 20, 61 [65] "Thorotrast". See also Deutsch, fn 27 above at 31.

of care in that he was given the wrong treatment and, in particular, that the Thorotrast injection was unjustifiable.

The basis of his claim was that the injection had served an experimental purpose, the results of which were used by the surgeon to further his research work. Indeed, the injection *did* give the surgeon an opportunity to monitor the effect of using Thorotrast, the risks of which were as yet unascertained. Hence, the motivation behind the experiment was non-therapeutic to the extent that the injections were not given for the patient's good. The court held in favour of the plaintiff, in a case which exemplified the fear of individuals being placed in a position in which their ability to consent freely was substantially impaired. The court was particularly worried about the plaintiff's status as a soldier and the possibility that he might feel that it was a part of his duty to consent to the intervention. This case illustrates the German antipathy to using 'captive individuals' for experimental purposes. It may be that the German response to issues raised by medical research is too restrictive. This will be discussed in a later chapter. For present purposes, attention is drawn only to the effect that Nuremberg had on the German people.⁵⁰ The self-doubt which arose as a consequence was not experienced by the Allies.⁵¹

Little is said of the Americans who, whilst being aware of the 'research' atrocities which were conducted in Japanese prisoner of war camps, chose to do nothing, and, instead, waited to see the outcome so that they could decide whether the results were useful. Details of the 'hidden Japanese experiments' which consisted of experiments, in biological warfare, emerged much later.⁵² The United States agreed to give the Japanese

⁵⁰See "Strafsache gegen Mulka und andere, Aktenzeichen 4 Ks 2 / 63", the so - called "Auschwitz trial" which began on December 20, 1963 in Frankfurt on the Main and which continued for 20 months and which was highly publicised. Countless school children from Frankfurt sat in on the trial which was visited by 20, 000 people. See Werle and Wandres, fn 48 above at 264.

⁵¹For example, the question concerning German identity continues to be the source of ongoing reflection and discussions especially in relation to the so-called 'German-Jewish dialogue' (*Deutsch-Jüdischen Dialog*). See for example Arning, M 'Ihre gebrochene Identität müssen die Deutschen wohl hinnehmen' *Frankfurter Rundschau* January 20, 1997 at p. 1.

⁵²Capron, A 'Human Experimentation' in Childress, J F et al., (eds) *Biolaw: A Legal Reporter on Medicine, Health Care and Bioengineering* (1986) at p. 229. See also McNeil, P *The Ethics and*

experimenters immunity from prosecution in exchange for the information derived.⁵³ Indeed, as this next section will show, the United States' record in relation to unethical research is less than 'squeaky clean'; yet it is a record for which they have never had to accept overt responsibility - as has Germany.

1.5. THE UNITED STATES

During the 1950s, military experiments were conducted in the United States that were not unlike those conducted by the Nazis⁵⁴ - the argument of 'military necessity'⁵⁵ was advanced in some cases. Examples of the experiments included the exposure of soldiers to radiation while a nuclear device was exploded in the Nevada desert⁵⁶ and the secret administration of dangerous drugs such as LSD to uninformed subjects by the Central Intelligence Agency (CIA).⁵⁷ In both cases the subjects were told that they were part of a study, but they were not informed of its precise nature.⁵⁸ The ethical norms laid down

Politics of Human Experimentation (1993) at pp. 23-26 and generally Williams, P and Wallace, D *Unit 731: Japan's Secret Biological Warfare in World War II* (1989).

⁵³On the grounds that trials of the Japanese experimenters would have led to the information obtained becoming available to other countries; immunity was therefore awarded by United States officials on the grounds of national security. McNeil, fn 52 above at 25. Unlike the Americans, however, the USSR prosecuted some of the Japanese involved. In December 1949, a Soviet military tribunal in Khabarovsk, Siberia charged twelve Japanese army personnel from Unit 731 with manufacturing and employing bacteriological weapons. Attempts to publicise the findings which arise during the course of the trial in the West failed, however. See Williams and Wallace, fn 52 above at 231-2.

⁵⁴For a highly informative appraisal of the history of the regulation of medical research involving human subjects in the United States, see Katz, fn 26 above, Levine, R J *Ethics and Regulation of Clinical Research* (1986), and Goldner, J A 'An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Professor Katz Seriously' (1993) 38 St Louis U L J 63. Note that during 'Operation Paperclip' which spanned the period between 1945-1955, the US military employed 765 German and Austrian scientists, engineers and technicians. Moreover, four defendants from the Nuremberg trial were at some point employed by the US military. See Annas and Grodin, fn 59 below at pp.106-107.

⁵⁵See *United States v. Karl Brandt* in Katz, fn 26 above at 295.

⁵⁶*Jaffee v. United States*, 633 F. 2d 1226 (3d Cir. 1981), *cert. denied*, 456 U.S. 972 (1982). See also Goldner, fn 54 above at 93 et seq.

⁵⁷*Central Intelligence Agency v. Sims*, 471 U.S. 159, 162 n.2 (1985).

⁵⁸*Begay v. United States*, 591 F. Supp. 991, 997-98 (D. Ariz. 1984), *aff'd*, 768 F. 2d 1059 (1985).

by the Nuremberg Code proved largely ineffective. Indeed, in some cases, American judges excelled in creatively circumventing the Code by holding it to be inapplicable.⁵⁹

By 1950, the Soviets exploded their first atomic warhead and the communists had come to power in mainland China. The foundations for the Cold War had been laid and America *had* to be prepared. Herein lay the justification for experiments comparable to those conducted in concentration camps by the Germans. Theoretically, the accusers at Nuremberg now stood accused. However, they retained a firm grip on the propaganda machine which, at the same time, maintained the level of defensive paranoia.⁶⁰

“The Cold War confrontation provided easy formulas to justify criminal action abroad and entrenchment of privilege and state power at home. Without the annoying need for thought or credible evidence, apologists on both sides could explain reflexively that, however regrettable, the acts were undertaken for reasons of “national security” in response to the threat of the cruel and menacing superpower enemy.”⁶¹

The American administration had stumbled across the perfect tool which would justify the experiments which they were carrying out. They could be portrayed as being ‘in the national interests’ - in other words, a necessary part of the war effort. In other words, the end could be justified according to the means.

⁵⁹See Annas, G J ‘The Nuremberg Code in U.S. Courts: Ethics Versus Expediency’ in Annas, G J and Grodin, M A (eds) *The Nazi Doctors and the Nuremberg Code* (1992) at 201 and 214.

⁶⁰Examples of Cold War paranoia include the Palmer raids where presumed foreign subversives were rounded up, imprisoned and expelled and the McCarthyism of the 1950s. “...the most significant support to the deeply embedded position of the military establishment in the culture of contentment was the perception that it was the bulwark against Communism, this being, as noted, the most obtrusive of the seeming threats to contentment. Fear of this was deep and fundamental in the psyche of the contented. Imperiled freedom, loss of liberty, was much cited; especially acute was the threat to private property.” Galbraith, J K *The Culture of Contentment* (1995) at 124. See also Walker, M *The Cold War* (1993) at pp. 160 et seq.

⁶¹“An ancillary convention comes into play as policy shifts for tactical reasons, or invocation of the threat is no longer needed, or its absurdity becomes too manifest to conceal. At that stage, the fears that were whipped up are seen as exaggerated by understandable Cold War passions. Now we will “change course” and be more realistic - until the next episode requires that the record be replayed. The routine is familiar to the point of boredom through the Cold War years.” Chomsky, N *World Orders, Old and New* (1994) at pp 1 - 2.

In 1960 the National Institutes of Health (NIH) awarded Boston University a contract to conduct a three year study on the practice of clinical research with reference to the legal, moral and ethical questions involved.⁶² The results were astonishing. Of fifty two institutions asked, only two had guidelines for human experimentation and only sixteen used consent forms. A National Commission for the Protection of Research Subjects was promptly set up with the task of drafting guidelines for research particularly as regards experiments on prisoners, children and the mentally ill. However, as has been suggested by some critics,⁶³ the guidelines which were eventually drawn up had more to do with the 'power to spend', namely, the practice of granting money subject to conditions. The concept of power as power over resources had arrived. It was a form of power with which the medical community, as well as the world community, was going to have to familiarise itself for years to come.

In 1962, Congress passed legislation which provided that all researchers involved in studies of new medication and seeking the approval of the Food and Drug Administration (FDA) must obtain consent from the research subjects. However, the provisions contained broad exceptions in the instances where obtaining consent was "*not feasible*" or not in the best interests of the subjects. The requirement for consent proved to be largely ineffective.⁶⁴

This was passed unnoticed because public scrutiny was otherwise occupied with the Cuban missile crisis. Despite the absence of armed combat, the message which pervaded the national consciousness was that this was a country still at war. The result was that scientists were left to their own devices. What followed was an accident waiting to happen.

A year later, headlines such as "*Nazi Tactics*" and "*How Doctors use Patients as Guinea Pigs*" appeared in New York newspapers thereby projected a relatively unknown

⁶²See Levine, fn 54 above at 322-25.

⁶³See Deutsch, E 'Die rechtlichen Grundlagen und die Funktionen der Ethik-Kommission' Vers R 89, 429.

⁶⁴See Goldner, fn 54 above at 94.

institution, the Jewish Chronic Disease Hospital into the limelight of public scrutiny.⁶⁵ The revelations which emerged culminated in a ruling of historical importance.

1.5.1. THE *HYMAN* CASE⁶⁶

It had been ascertained previously that, if healthy individuals were injected with cancer cells from another individual, the healthy person would promptly reject the transplant. However, rejection of the transplant was delayed when a person who was, himself, suffering from cancer was injected with the same cells. The doctor involved, Dr Southam, wanted to ascertain whether the foreign cancer cells survived longer in cancer patients as the result of the pre-existing cancer or as the result of the patient's general weakness and debilitation. Dr Southam engaged a young doctor called Dr Mandel, who agreed to carry out the experiment under his direct supervision. The experiment, which was funded by the United States Public Health Service and the American Cancer Society, had received the approval of both the hospital's grievance committee and the hospital's board of directors.

On the 16th of July 1963, cancer cells were injected into 22 hospitalised patients as part of a study of the immune system's response to cancer. Consent of the research subjects was obtained only verbally. Furthermore, they were only told that they would be receiving some cells; they were *not* told that these cells would be cancer cells.⁶⁷ The doctors defended their actions by asserting that the distinction was of no consequence to the patients, that it was not a cause of increased risk to the patients and, further, that the precise nature of the foreign cells was irrelevant to the bodily reactions which could be expected to occur. Why then were the patients not injected with normal cells? This question was seemingly never addressed.

⁶⁵Langer, E 'Human Experimentation: New York Verdict Affirms Patient's Rights' (1966) 151 *Science* 663-66 as reproduced in Gorovitz, S, Macklin, R, Jameton, A L, O'Connor, J M, Sherwin, S (eds) *Moral Problems in Medicine* (2nd edn, 1983) at p. 626.

⁶⁶15 N.Y. 2d. 317, 206 N.E. 2d. 338; 258 N.Y. 2d 397 (1965).

⁶⁷Schlaudraff, fn 24 above at 40.

It is arguable that, by modern American standards, the experimenters were guilty of battery for which the hospital would have been liable on the grounds that there was a lack of consent as to the injection of cancer cells. Furthermore, the members of the board of directors might also have incurred liability for knowingly permitting such assaults to take place. However, this scenario never materialised as the case did not involve a resolution of the propriety or the technical aspects of the tests.

The legal case arose when Mr Hyman, a member of the hospital's own board of directors, questioned the permissibility of their research practices by asking the court to determine whether he was entitled, as a matter of law, to inspect the records of the hospital to investigate allegations of illegal and improper experimentation on patients. Mr Hyman's application is best understood as a fight to drag research from behind hospital doors out into the open - away from secrecy and towards greater accountability.

The Court of Appeals of New York decided to allow an order for Mr Hyman to inspect records of a predominantly financial or administrative nature.⁶⁸ However, the court did not extend the terms of the order to allow the petitioner to inspect and make copies of the records of the research subjects, the death certificates of those who died or of their pathological reports, slides and laboratory data. The court maintained that the information should not be available to the petitioner for inspection and photocopy since, as a layman, he was under no legal duty to refrain from disclosing such information to others.⁶⁹

In overturning the decision of the Courts of Appeal, the Supreme Court granted Mr Hyman's petition as to the items which he had requested by maintaining that, as a member of the board of directors, he had a legitimate interest to inspect and copy all records in the possession or control of the corporation. These records included the minutes of the board of directors, a report of the executive director, a report of a doctor

⁶⁸This included copy books of account and fiscal records as well as rules and regulations governing handling of patients.

⁶⁹15. N.Y. 2d 317; 206 N.E. 2d 338; 258 N.Y. 2d 397 See in particular the persuasive reasoning by Morris Ploscowe and Harvey I. Sladkus for the respondent.

to the medical board and the charts and records of the patients who had submitted to the tests.

It is interesting to note that whereas no legal action was taken against the doctors⁷⁰ the Regents of the University of the State of New York, whose responsibility it was to license the medical profession,⁷¹ held that that the two physicians were guilty of “unprofessional conduct” and of “fraud and deceit in the practice of medicine” insofar as they had failed to inform the research subjects fully of what they were doing. Despite their licenses being suspended for the period of one year, both physicians continued to practice, albeit on probation.⁷² The case has been described as being a very important milestone in that the *manner* of carrying out the experiment was questioned as opposed to its propriety.⁷³ However, the main significance for present purposes lies in its illustration of attitudes to the conduct of research at that time.

Much of the testimony, which was introduced during the course of the trial by well known researchers, was to the effect that the practices of Southam and Mandel did not differ materially from those employed by their peers. Elinor Langer quotes one of the lawyers involved in the trial as stating that, “If the whole profession is doing it...how can you call it ‘unprofessional conduct’ ?”⁷⁴ The official party line, which did not deviate from the spirit behind this remark, was put rather more delicately. The Public Health Service simply stated that,

“...in supporting extramural clinical investigations, it is the position of the Public Health Service that proper ethical and moral standards are more effectively safeguarded by the processes of review and criticism by an investigator’s peers than by regulation.”

⁷⁰For any involvement of the legal process was for the purposes of discovery regarding information surrounding the experiment only.

⁷¹Langer describes the Board of Regents as consisting of “...15 individuals elected by joint resolution of the two houses of New York’s legislature for terms of 15 years. The Regents have jurisdiction over all education in the state, public and private, and over all licensed professions excluding law. The three Regents most intimately involved in this decision were the three members of a special committee on discipline.” Langer E, fn 65 above at 626-627.

⁷²Langer, fn 65 above at 627.

⁷³See Beecher, H K *Research and the Individual* (1970) at p. 170.

⁷⁴See Langer, fn 65 above at 629.

In other words; '*members of the scientific community unite*'. Elinor Langer's article, which appeared shortly afterwards, seemed to criticise the statement by stating that it was too theoretical. However, she ended up by towing the party line by arguing that,

“...given the tremendous growth and variety of medical research involving human beings, if it is not done by the scientific community, someone else will start to do it. The New York Regents may be only the beginning.”⁷⁵

It was of course not *the* beginning, as the attempt to draw up guidelines for the conduct of research involving human subjects had begun far earlier. It was, however, *a* beginning to the extent that it began to unveil a code which some heralded as one of honour but which others damned as one of secrecy.

Could Mandel have refused to take part or was he a modern day Lydgate? The facts surrounding the case suggest that he was not acting under duress. Instead, he emerges as the eager young resident, keen, committed and as ambitious as Dr Rascher. Mandel was also concerned about what he later referred to as the “insufficient medical attention to the long term, chronically ill patients”⁷⁶ and believed that the experiment would improve their care. As a resident, he also had an eye for an opportunity to bolster his career. Indeed, as it later emerged at trial, he “looked forward to the possibility of a more prolonged collaboration with the Sloan-Kettering company which would contribute to upgrading his own institution.”⁷⁷ In a vote for the chaplaincy of Middlemarch, Lydgate backed Mr Tyke, going against his belief that Mr Farebrother would be more suitable. Mr Tyke was the nominee of the ubiquitous Mr Bulstrode, who had promised to finance a new hospital. What more could an aspiring young physician wish for?⁷⁸

⁷⁵See Langer, fn 65 above at 630.

⁷⁶See Langer, fn 65 above at 628.

⁷⁷Ibid.

⁷⁸Eliot, fn 1 above at 207 et seq.

1.5.2. BEECHER'S ARTICLE

In June 1966, Beecher, of the prestigious Harvard Medical School, wrote an article which influenced the debate in the United States profoundly.⁷⁹ He cited 22 instances between 1950-1965 where unethical procedures had been adopted. Many patients were unaware that they were the subjects of experimentation. Those that had been informed were not told of the actual risks involved. However, perhaps most alarming of all were the cases where known effective treatment was, in fact, withheld.

An example of this was a study which was carried out on 109 American Servicemen. Treatment of streptococcal upper respiratory infection was withheld despite the knowledge that the consequent development of rheumatic fever might be prevented by the use of penicillin. One group of servicemen was given placebos while patients in another group received penicillin. Two patients in the placebo group subsequently developed acute rheumatic fever and one was diagnosed as having acute nephritis; no cases occurred in the treated group.⁸⁰

In another study, 408 patients were divided into separate groups in order to monitor the relapse rate of typhoid fever when it was treated in two ways. It had been recognised in a previous study that withholding the known effective treatment was dangerous to life. Nevertheless, established treatment was withheld, resulting in the deaths of twenty three patients who would probably not have died had they received specific therapy.⁸¹

A further project involved the transplantation of melanoma cells from a girl, who was dying from the disease, to her mother, "in the hope of gaining a little better understanding of cancer immunity and in the hope that the production of tumour antibodies might be helpful in the treatment of cancer patients". The daughter died on

⁷⁹Beecher, H K 'Ethics and Clinical Research' (1966) 274 New Eng LJ Med 1354.

⁸⁰Beecher, fn 79 above at 1356.

⁸¹Beecher, fn 79 above at 1356.

the day after the transplantation and her mother died fifteen months later from melanoma that was assumed to have metastasised from the transplanted tumour.⁸²

Beecher concluded that the best protection for patients lay in the conscience of the investigator. Research without publication is, however, of little value. Accordingly, he argued that publishers ought to stress that the proprieties had been observed. He thereby placed responsibility on the editor as well as on the researcher, hoping that a better protection would ensue in that a researcher would be deterred from employing unethical practices for fear of not having his results published;

“Even though suppression of such data (by not publishing it) would constitute a loss to medicine, in a specific localized sense, this loss, it seems, would be less important than the far reaching moral loss to medicine if the data thus obtained were to be published.”⁸³

This statement is as appropriate now as it was in 1966. There can be no doubt that in the current ‘publish or perish’ climate, there is substantial pressure on doctors to come up with original research work in order to further their careers. The tension between the ‘scientist’ and the ‘patient care’ doctor was an issue which Beecher had already anticipated in 1966;

“...medical science has shown how valuable human experimentation can be in solving problems of disease and its treatment; one can therefore anticipate an increase in experimentation; and the newly developed concept of clinical research as a profession (for example, clinical pharmacology) and this, of course, can lead to unfortunate separation between the interests of science and the interests of the patient.”⁸⁴

Increasingly, hospital medicine is moving away from patient care towards the ‘You are what you write’ ethos.

⁸²Beecher, fn 79 above at 1358.

⁸³Beecher, fn 79 above at 1359; Although he admits that it might be argued that, because of their intrinsic value, such data should not be wasted but should be published with stern editorial comment; he does not, however, share this view.

⁸⁴Beecher, fn 79 above at 1355.

However, Beecher failed to take into account the possibility of publication bias whereby editors of scientific journals publish only research with positively significant results. The existence of such bias can have consequences which are far reaching; researchers experience difficulty in getting negative results published. The drawbacks of this are substantial. If negative results are not published, the hypothesis which led to the research being carried out in the first place can not be eliminated from that specific area of inquiry. Thus, the unnecessary duplication of medical research trials is encouraged. A register of clinical trials might well eliminate such difficulties.

Beecher's article made a major impression. However, it is difficult to see why the impact was as substantial as some commentators believe.⁸⁵ Regarding Beecher's article, it has been stated that it,

"...struck the medical research community in the US like an exploding fragmentation bomb. All manner of investigators and research projects from the military and government laboratories were hard hit by his very specific and well documented illustrations. The reprinted letters to the editor of the *New England Journal of Medicine* indicate the scope of the reaction to it."⁸⁶

Whereas it is arguable that the letters indicated the depth of the reaction, it is questionable whether they indicated the appreciation of the *ethical* element in research. Beecher himself pointed out that it was based on the misunderstanding that his paper was a "sweeping indictment of all human experimentation". This, he argued, was not the case as he was in favour of promoting the development of research as long as it was carried out in an ethical manner.⁸⁷

⁸⁵ McNeil, fn 52 above at 60. This is discussed in further detail below.

⁸⁶ Introduction to Part V 'Medical Experimentation on Human Subjects' in Reiser, S J, Arthur, J, Dyck and Curran, W J (eds) *Ethics in Medicine-Historical Perspectives and Contemporary Concerns* (1977) at p. 255.

⁸⁷ "I should like to affirm that American medicine is sound and most progress in it soundly attained". Beecher, fn 79 above at 1354.

At least some of his critics appreciated this;

“It will be particularly unfortunate for patients if physicians are not encouraged to improve their understanding of disease by properly safeguarded human studies. What is needed is not less human experimentation but more good investigation in man.”⁸⁸

Two traditional attitudes exist concerning the *Hyman* case and Beecher’s article. First, *Hyman* is often cited as an example of unethical research. This may be so but its primary significance is as an illustration of the attitudes to secret research at that time. Secondly, Beecher’s article is widely described as having had an ‘incredible impact’. On whom? It certainly had an impact on the medical profession; but the general public was largely untouched by it. The readership of the *New England Journal of Medicine* is more selected than some might imagine.

In my opinion, the impact of Beecher and the judgment in *Hyman* are best understood when they are seen as cumulative. Each represented an individual strand of rope - that is circumstantial evidence - which took unethical research out of the closed scientific shop and into the field of public debate.⁸⁹ The fact that the evidence was circumstantial does not detract from its value - in certain cases, circumstantial evidence can be the most cogent form of evidence.⁹⁰ Questions arise as to why unethical research had remained undetected for so long. It is widely accepted that common knowledge is often shared in silence.⁹¹

⁸⁸ Silverman, W A ‘Letters to the editor in Response to Beecher’s Essay’ (1966) 275 New Eng L J Med 791.

⁸⁹“One strand of the cord might be insufficient to sustain the weight, but three stranded together may be quite of sufficient strength. Thus it may be in circumstantial evidence - there may be a combination of circumstances, no one of which would raise a reasonable conviction or more than a mere suspicion; but the three taken together may create a conclusion of guilt with as much certainty as human affairs can require or admit of.” *Per* Pollock CB in *R v. Exall* (1886) 4 F & F 922 at p. 929.

⁹⁰“It is no derogation of evidence to say that it is circumstantial.” *R v. Taylor, Weaver and Donovan* (1928) 21 Cr App Rep 20 (CA).

⁹¹“In most cases they were things which people do not talk about for fear of exposing themselves to thoughtless ridicule. I was amazed to see how many people have had experiences of this kind, and how carefully the secret was guarded.” Jung, E *The Structure and Dynamics of the Psyche, Collected Works* (Vol. VIII, 1960, Hull, R F C (tr)) at p. 420.

Antipathy to publication was based on more than the fear of ridicule. The scientific community is no different from any other community and is subject to the same unwritten codes of etiquette. A scientist being seen to rock the boat could be labelled a troublemaker and the potential for damage to his career prospects should not be underestimated. Beecher was unaffected by such considerations and was able to bring cases to light by reason of his professional standing; his career had spanned 36 years.⁹²

A comparable example of an individual reaching the decision that something needed to be written about a certain phenomenon is to be found in the area of child abuse. In 1962, Kempe drew attention to battered child syndrome and its high mortality rate.⁹³ So strong was the disbelief that such a situation could exist in a modern society that it had previously been misdiagnosed, ignored or simply swept under the carpet.⁹⁴

The prevailing theme in both examples is that of disbelief. Nobody had believed that people were doing these things. The reason why it existed was that it was done in secret. Unethical research could not exist without secrecy. Beecher and Kempe both fought for openness, for greater transparency.⁹⁵ This is the motivation behind establishing research ethics committees⁹⁶ which ensure that all research is exposed to the public gaze.

⁹²See *Who's Who in Science - From Antiquity to the Present* (1968) at p. 142.

⁹³See Kempe, C H *et al* 'The Battered Child Syndrome' (1962) 181 J Amer Med Ass at 17.

⁹⁴Caffey, J 'Multiple fractures in the long bones of children suffering from chronic subdural hematoma' (1946) 56 Amer J Roentgenol 163. The author believed that he was dealing with natural disease.

⁹⁵It is probable that they broke the code of silence in order to restore faith in intellectual integrity rather than to point the finger at individuals.

⁹⁶Which I will be discussing in detail in a later chapter.

1.6. THE UNITED KINGDOM

1.6.1. PAPPWORTH'S BOOK

A years after Beecher's article in the *New England Journal of Medicine*, a book entitled 'Human Guinea Pigs'⁹⁷ by a General Practitioner, Maurice Pappworth was published in the United Kingdom; this also contained allegations of unethical research. Despite Pappworth's reputation as the *enfant terrible* of the medical establishment the impact of the book was relatively slight compared to the effect which Beecher's article made in the United States.⁹⁸ The book ought to have provoked greater public interest because experiments were being carried out mainly on hospital patients - that is, the public; and this was seen as the most ethically disturbing aspect. The public, however, was uninterested.⁹⁹ It would have been an entirely different matter had the research subjects been animals.¹⁰⁰

1.7. THE BIRTH OF INSTITUTIONAL REVIEW

1.7.1. THE DEVELOPMENT OF INSTITUTIONAL REVIEW BOARDS (USA)

Gradually, people's awareness increased to the extent that unethical research was not restricted to the atrocities which came to light during the Nuremberg trials. A body of opinion had begun to emerge which held that, although both the Nuremberg Code (1947) and the Declaration of Helsinki (1964) provided clear guidelines as to the conduct of human experimentation, there was a lack of effective control. Both

⁹⁷(1967).

⁹⁸See McNeil, fn 52 above at 66.

⁹⁹McNeil, fn 52 at 69.

¹⁰⁰See further.

documents emphasised the investigator's duty to safeguard the rights and welfare of the subjects; however, no reference was made to public or peer review.¹⁰¹

James Shannon, the then Director of the U.S. National Institutes of Health (NIH), had become increasingly uneasy about the implications of the swift changes which were beginning to shape the development of research. His alarm resulted from the *Hyman* case and the unsuccessful transplantation of the kidney of a chimpanzee into a human being. In this case, the surgeon had not consulted his peers as to the nature or possible effectiveness of the operation. He had obtained the consent of the patient yet there was no acceptable evidence to suggest that the operation would be a success or that it would provide new scientific information.¹⁰² The project had been partially funded by the NIH;

“Since such investigation departs from the conventional patient-physician relationship, where the patient's good has been substituted for by the need to develop new knowledge,...the physician is no longer in the same relationship...and indeed may not be in a position to develop a purely or wholly objective assessment of the moral nature or the ethical nature of the act which he proposes to perform.”

¹⁰³

Moreover, he was particularly concerned about the way in which the doctor/patient relationship was being altered. In September 1965 he sought advice from the National Advisory Health Council (NAHC). The deliberations of the NAHC culminated in a resolution adopted in December 1965 which provided that the Public Health Service should support clinical research involving human subjects only where an investigator's research had been reviewed by his institutional associates.

The recommendations of the NAHC formed the basis of the first federal policy statement on protection of human subjects which was issued in February 1966 by the Surgeon General of the United States Public Health Service (USPHS). This policy made prior

¹⁰¹See Levine, fn 54 above at 322.

¹⁰²McNeill, fn 52 above at 57.

¹⁰³(NAHC 1965) Reported in Capron, A M ‘ Human Experimentation’ in Veatch, R M (ed) *Medical Ethics* (1989) at p. 130.

review of federally supported research mandatory¹⁰⁴ and was later revised in July 1966. The requirement was extended to cover all USPHS grants. The policy included the requirement for institution-wide assurances which would cover all grant proposals emanating from a single institution as opposed to individual assurances. A subsequent revision in December 1966 upheld the responsibility of such institutions to ensure that investigations were carried out in a manner which accorded with *the laws of the community in which the investigations were conducted*. This would have to include due consideration to the ethical implications of the investigation.¹⁰⁵ Despite this, the effect of the measures introduced in 1966 was to ensure that the medical research community had first refusal as to the approval of research protocols *with a little help from their friends* - the emphasis being on the word *little*.

Institutional Review Boards (IRB) were established, whose primary function it would be to evaluate proposals for medical research. These proposals could only be developed into actual trials involving human subjects when a researcher had received the approval of an IRB. The House of Delegates of the American Medical Association echoed this requirement by endorsing the principles established by the declaration of Helsinki and by issuing its *Ethical Guidelines for Clinical Investigators* as part of its Principles of Medical Ethics.¹⁰⁶

Whereas the committees established in pursuance to the USPHS legislation were usually made up entirely of scientists and physicians, the concept of the research ethics committee was considered to be wide open to innovation and the phenomenon of 'ethics by committee' gradually emerged.¹⁰⁷ Influenced by the reforms taking place in the

¹⁰⁴"No new, renewal, or continuation research or research training grant in support of clinical research and investigation involving human beings shall be awarded by the Public Health Service unless the grantee has indicated in the application the manner in which the grantee institution will provide prior peer review of the judgment of the principal investigator or program director by a committee of his institutional associates." February 8, 1966. See Levine, fn 54 above at 323.

¹⁰⁵See Levine, fn 54 above at 323.

¹⁰⁶See Goldner, fn 54 above at 92.

¹⁰⁷"There are several forms of medical decision-making by interdisciplinary committees. These committees include...institutional ethics committees (IECs) established without any legal obligation by many hospitals and some nursing homes to help review ethical policies and practices; infant care review committees (ICRCs) established pursuant to the "Baby Doe" regulations to review the quality

United States, both the United Kingdom and Germany quickly followed suit. The practice of submitting proposals for research ethics approval evolved and was later embodied in the Revised Declaration of Helsinki (1975-83).

As regards the composition of such committees, further guidelines requiring that committee membership ought to reflect, “*varying backgrounds...[and possess] competencies...in terms of institutional regulations, relevant law, standards of professional practice, and community acceptance*”¹⁰⁸ were issued in 1969; these were revised in 1974 and mandated specific composition of and numerical requirements for committee membership.¹⁰⁹ The concept of the committee as ‘surrogate for the community’ evolved.¹¹⁰

The reforms which were taking place were not unopposed. Jay Katz writes about a letter from Owen H. Wangensteen to Senator Walter F. Mondale in January 28, 1968¹¹¹ concerning Mondale’s proposal to Congress of creating a commission to adjudicate the Social and Ethical implications of Health Science Research and Development,

“Senator, I would urge you with all the strength I can muster to leave this subject to the conscionable people in the profession who are struggling valiantly to advance medicine. We are living through an era in which the innovator is often

of care given to seriously ill newborns under some circumstances; diagnosis committees established to determine a diagnosis that triggers an ethical and legal consequence (like “terminal illness”) has been properly confirmed; medical-legal malpractice review panels established by state law in some states and by medical and legal societies in others to provide screening of potential malpractice actions; the Recombinant DNA Advisory Committee (RAC) established by federal law to review research involving DNA; presidential commissions appointed by the President under acts of Congress to investigate and help establish national policy on matters of interdisciplinary concern and parallel state commissions to establish state policy.” Furrow, B R, Johnson, S H, Jost, T S, Schwartz, R L *Health Law: Cases, Materials and Problems* (3rd edn, 1996) at p. 1193.

¹⁰⁸See Levine, fn 54 above at 324 (quoting guideline revisions dated May 1, 1969).

¹⁰⁹See Levine, fn 54 above at 324.

¹¹⁰“...the requirement for non-employee members on organizational committees is an essential protection against the development of insular or parochial committee attitudes, that assists in maintaining community contacts, and would augment the credibility of the committee’s independent role in protection of the subject...It should be emphasized that the term community is intended to be applied in the sense of the larger community served by the organization, not necessarily the smaller community involved in a particular activity or project.” 39 Fed. Reg. 18, 915 (1974).

¹¹¹*Hearings on S.J. Res. 145 before the Subcommittee on Government Research of the Senate Committee on Government Operations, 90th Congress, 2d Session 98-99 (1968) in Katz, fn 26 above at 310-311.*

under suspicion, being second-guessed by self-appointed arbiters more versed in the art of criticism than in the subject under scrutiny. We need to care lest the wells of creativity and the spring of the mind of those who break with tradition are not manacled by well-intentioned but meddlesome intruders.”¹¹²

Katz was just such a meddlesome intruder. The revelations which appeared in his book, *Experimentation with Human Beings*,¹¹³ once again shocked academics and the public alike. His book included outlines of two studies, which echoed times past. However, this time there was no *régime* on which to pin the blame - or was there ?

The experiments conducted in Tuskegee had been going on for some forty years before they came to light in 1972.¹¹⁴ In a federally sponsored study, some four hundred poor black males suffering from syphilis were deliberately left untreated for decades in order to study the natural history of the untreated disease. The research subjects were not informed of their participation in the study; moreover, most did not know that they had the disease, believing instead that they were receiving ordinary medical care. Further experiments outlined included a hepatitis study involving residents of the Willowbrook State School in New York, which was an institution for mentally disabled children and a study where either placebos or oral contraceptives were given at random to poor Mexican-American women who had come to a San Antonio clinic for contraceptive advice.

It has been argued that it was this book which provided the impetus for the legislation in the form of the National Research Act 1974.¹¹⁵ But, in fact, the credit should go to Beecher who had been one of Katz's teachers at Harvard Medical School and had delivered lectures on anaesthesia and who had made “quite an impression” on Katz.¹¹⁶ Katz contacted Beecher years later having acquired an interest in human experimentation from a monograph of Beecher's entitled *Experimentation in Man*. It was this book

¹¹²See Levine, fn 54 above at 310. See also *Moore v. University of California* (1988) 51 Cal App 3d 1230 (Cal CA).

¹¹³Katz, fn 26 above.

¹¹⁴See Jones, J H *Bad Blood: The Tuskegee Syphilis Experiment* (2nd edn, 1993).

¹¹⁵See Goldner, fn 54 above at 94.

¹¹⁶See Katz, J ‘Ethics and Clinical Research Revisited: A Tribute to Henry K. Beecher’ (1993) 23 Hastings Centre Report 32.

which was to form the basis of the article which later appeared in the *New England Journal of Medicine*. Beecher had unwittingly found a perfect disciple in Katz, whose apprenticeship was to culminate in an effect which Beecher's article merely aspired to - that is, guiding the administrative hand towards the nettle of reform.¹¹⁷

1.7.2. THE NATIONAL RESEARCH ACT 1974

The National Research Act 1974 established the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. The task of the Commission was to conduct an investigation into the basic ethical principles governing the conduct of medical research involving human subjects.¹¹⁸ Thus, in 1979, the Belmont Report was published.¹¹⁹ As well as providing an ethical basis upon which the regulation of medical research could be regulated, the Report firmly established the requirement to obtain the approval of an IRB.¹²⁰

The current regulatory position in the United States is that, whereas IRB approval is required before any federally funded research project may proceed, in practice institutions, such as medical schools and research hospitals, have undertaken to conform to the regulations and have further implemented these regulations to apply to all forms of research, irrespective of the source of funding. Supplementing these rules are requirements issued by the Food and Drug Administration which provide that IRB

¹¹⁷See Katz, fn 116 above at 31-39.

¹¹⁸Supported by the then Department of Health, Education and Welfare. See Goldner, fn 53 above at 96.

¹¹⁹*The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research*, U.S. Dep't of Health, Educ., and Welfare, Pub. No. (OS) 78-0012, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1978).

¹²⁰Revisions of the regulations were proposed in 1979 which predated hearings which were held by the Department of Health, Education and Welfare and later by the President's Commission. Further regulations were implemented in 1981 which were then extended in 1991 to apply to research funded by most other federal agencies. "...each entity which applies for a grant or contract which involves the conduct of biomedical or behavioral research involving human subjects submit...assurances satisfactory to the Secretary of Health, Education and Welfare that it has established a board (to be known as an Institutional Review Board) to review biomedical and behavioral research involving human subjects conducted or sponsored by the institution in order to protect the rights of the human subjects of research." 42 U.S.C § 289 (a) (1988) cited in Goldner, fn 53 above at 98.

review must be sought for all research related to the marketing of drugs and medical devices.¹²¹

Approval by research ethics committees is now commonly regarded as essential for research conducted not only in the United States but throughout most of the European Union as well. Despite the fact that this practice has become widely accepted and standardised, some questions remain.¹²²

1.7.3. THE DEVELOPMENT OF RESEARCH ETHICS COMMITTEES IN THE UNITED KINGDOM

The historical development of research ethics committees in the United Kingdom began with guidelines for the conduct of research which were issued by the Medical Research Council (MRC) in 1963.¹²³ The report does not, in fact, refer to committee review of research, but its importance lies in its having formed the basis for later discussions on research involving human subjects. The MRC guidelines were reconsidered in 1967 by the Royal College of Physicians which recommended that all research carried out in medical institutions ought to receive the approval of an ethics committee. However, in similar vein to the development in the United States, the recommendation stipulated that ethics committees should be composed solely of independent doctors; the foundation for monopolising the review process were put firmly in place.¹²⁴

A formal attempt to regulate experimentation was introduced by the Medicines Act 1968.¹²⁵ The Act provides *inter alia* that clinical trials on patients may progress only

¹²¹21 C.F.R. § 46. 103 (1992) See Goldner, fn 54 above at 99.

¹²²See Chapter Five.

¹²³'Responsibility in investigations on human subjects' (1963) 177 BMJ 177 which has now been replaced by Medical Research Council, *Responsibility in Investigations on Human Participants and Material and on Personal Information* (1992).

¹²⁴'Report of the Committee Appointed by the Royal College, Supervision of the ethics of clinical investigations in institutions' (1967) 3 BMJ 429-30. Also see Dodds-Smith, I 'Clinical Research' (1992) in Dyer C (ed) *Doctors, Patients and the Law* (1992) at p. 153.

¹²⁵This provides that clinical trials involving patients may proceed once a Clinical Trial Certificate (CTC) is obtained. In applying for such a licence, a company must disclose the results of

once the Committee on Safety of Medicines (CSM), which was established under s.4 of the Act, gives its approval.¹²⁶ Two observations may be drawn from the implementation of the Medicines Act. First, it is unfortunate that, although the Act provides a statutory framework for the regulation of clinical trials of new drugs, it does not allow for research on innovative medical procedures within that framework.¹²⁷ Secondly, whereas the 1968 Act recognises the existence of research ethics committees, it makes no actual provision for them.

In 1973, the Royal College of Physicians released further recommendations concerning the composition and function of research ethics committees, the consequence of which was that the Department of Health issued a circular which implemented most of the College's proposals.¹²⁸ The Royal College released detailed guidelines in 1984¹²⁹ which laid down the constitution and the functions of research ethics committees. These guidelines were further revised in 1990¹³⁰ and these, in conjunction with the 1975 Department of Health guidelines, set the standard for ethics committees in the United Kingdom. The 1975 guidelines were, however replaced by a Department of Health circular issued in 1991.¹³¹ The United Kingdom has passed the Medicines (Applications

preliminary research and those acquired through tests on animals. In practice, most applicants for CTCs are pharmaceutical companies, being responsible for sponsoring the majority of research; individual physicians may apply for CTCs but the procedure is for them to apply for a certificate under the Doctors and Dentists Exemption Scheme (DDX). Note: a CTC is not required for studies in healthy volunteers. Also, see Wiffen, P 'A Guide to the Licensing System for Medicines (Medicines Act 1968 and Amendments)' in Kennedy, I (ed) *The Manual for Research Ethics Committees* (1992).

¹²⁶A new scheme was introduced in 1981 under the provisions of the Medicines (Exemption from Licences) Order 1981 (SI 1981 no. 1964) which in effect speeds up the process whereby researchers may obtain a response as to whether their requests for certificates will be granted allowing them to carry out the research.

¹²⁷See Brazier, M *Medicine, Patients and the Law* (2nd edn, 1992) at p. 429.

¹²⁸HSC (15) 153 (1975).

¹²⁹Royal College of Physicians *Guidelines on the Practice of Ethics Committees in Medical Research*, (1984).

¹³⁰Royal College of Physicians *Guidelines on the Practice of Ethics Committees in Medical Research involving Human Subjects* (2nd edn, 1990) and Royal College of Physicians *Research Involving Patients* (1990). Note that the RCP guidelines were revised again in 1996. See Royal College of Physicians *Guidelines on the Practice of Ethics Committees in Medical Research involving Human Subjects* (3rd edn, 1996).

¹³¹For an analysis of the practical effect of the guidelines see the Chapter Five.

for Grant of Product Licences - Products for Human Use) Regulations¹³² which implements E. C. Directive 91 / 507 / EEC. This provides that all phases of clinical investigations must be undertaken “in accordance with good clinical practice”. A working definition of “good clinical practice” is provided by the European Guidelines on Good Clinical Practice¹³³ which go into considerable detail as regards the practice of clinical research.

Whereas there is no statute regulating medical research on human subjects in the United Kingdom, there are specific guidelines which govern the establishment, role and functions of Local Research Ethics Committees (LRECs) in the NHS.¹³⁴ These state that each LREC ought to invite any drug companies involved to submit their research proposals to them; but there is no obligation to accept this invitation.¹³⁵ It is stated additionally that,

“By agreement, an LREC may also advise on the ethics of studies not involving NHS patients, records or premises, carried out for example by private sector companies, the Medical Research Council or universities.”¹³⁶

It should be noted that a number of ‘informal’ ethics committees have been established; these include those set up by universities, private hospitals and the pharmaceutical companies. It is, therefore, necessary to distinguish medical research carried out within the NHS from that undertaken elsewhere.

1.7.3.1. RESEARCH WITHIN THE NHS

¹³²S I 1993 No. 2538.

¹³³Notes for Guidance on Good Clinical Practice for Trials on Medicinal Products in The European Community (E.C.) 1990 III / 3676 / 88 - EN. [Approved July 1990; effective July 1991]. Also published in *Pharmacology & Toxicology* (1990) 67 at pp. 361-372.

¹³⁴Local Research Ethics Committees, Department of Health (1991) replacing HSC (15) 153 (1975).

¹³⁵“Even where there is no NHS involvement the body conducting the research should be encouraged to submit its proposals to the LREC for advice.” Local Research Ethics Committees, Department of Health (1991) at p. 10. Note that there are also guidelines concerning multi-centre research which establish regional multi-centre RECs in England and Wales (see HSG (1997) 23) and a national multi-centre REC in Scotland (see NHS MEL (1997) 8). A personal inquiry indicates that Northern Ireland does not, as yet, have any provisions concerning such committees. See Chapter Five at Section 5.6.1.

¹³⁶See fn 135 above at 6.

The Department of Health 1991 circular applies solely to the NHS in England and Wales and provides that all Health Authorities in the NHS must set up LRECs to which all NHS trials must be submitted. In Scotland, the position is governed by the Scottish Office Home & Health Department guidelines.¹³⁷

The obligation on a Health Authority to set up a research ethics committee to monitor research on human subjects is not a legal requirement *per se*.¹³⁸ The 1991 guidelines are in the form of a *circular* only. Guidelines which have been produced by an authority which has been established by specific legislation¹³⁹ have the force of law. In the absence, however, of legislation directly referring to research ethics committees, the 1991 guidelines can only be regarded as persuasive.¹⁴⁰

1.7.3.2. RESEARCH IN THE PRIVATE SECTOR

As I have already stated, the 1991 circular provides that pharmaceutical companies in the private sector may be invited to submit their research proposals to research ethics committees set up by district health authorities. However, for the most part, these companies tend to prefer submitting their proposals to their own ethics committees. There is no central governing body which is responsible for the regulation of medical research carried out in the private sector; in particular, there is no central committee to whom private sector RECs are accountable. A direct consequence of this is that there is no official body which scrutinises experimental treatment in the private sector.

However, the position in relation to clinical trials is markedly different. The Association of British Pharmaceutical Companies (ABPI) together with the Association of Independent Clinical Research Contractors (AICRC) have drafted a series of voluntary

¹³⁷Local Research Ethics Committees; Edinburgh 1992 (GEN) 3 replacing 1976 (GEN) 38.

¹³⁸See Kennedy, I 'Research Committees and the Law', fn 125 above.

¹³⁹E.g. the Human Fertilisation and Embryology Authority established by the Human Fertilisation and Embryology Act 1990.

¹⁴⁰Cf Ganz, G *Quasi-Legislation* (1987) at p. 75 et seq.

codes of practice which govern the conduct of clinical trials and the use of volunteers therein. The essential elements of the code of practice is that a written contract must be drawn up for the research subject which sets out the nature of the medication as well as the remuneration which they will receive. The code also stipulates that a no-fault compensation scheme should be set up so that, in the event of mishap, subjects are spared having to surmount the causal hurdle in proving negligence at trial.¹⁴¹ The irony of the situation is that research subjects are less well protected within the NHS where such schemes are by no means standard. However, no-fault compensation schemes appear to represent the norm for most commercial clinics. In effect, the code of conduct provides a contractual obligation on behalf of a pharmaceutical company to set up an insurance scheme.

Pharmaceutical companies regulate themselves very strictly. Since their role of drug companies is to produce better and safer medicines as well as to make a profit, the last thing that they would want would be to cause harm and, co-incidentally, to receive bad publicity. The average cost of obtaining a licence for a new drug amounts to over £200M; it is unlikely that a drug company would wish to risk its investment by sponsoring dubious research practices.¹⁴²

In practice, however, there is cause for concern as to whether the system is watertight. It has been argued that the APBI code in particular, has not acted as an effective deterrent.¹⁴³ In maintaining this position, some writers have cited examples of companies who, having fallen foul of the codes of conduct by offering financial inducements to doctors and by allowing promotional trials devoid of scientific merit to go ahead, have only been moderately rebuked.¹⁴⁴ In 1986, Bayer UK were suspended for a year following allegations that it encouraged its sales representatives to induce

¹⁴¹*The Association of British Pharmaceutical Industry, Clinical Trial Compensation Guidelines* (1991).

¹⁴²Dr Tim Madd of Guys Drugs Research Unit, Radio 4, October 1993.

¹⁴³Herrxheimer, A and Collier, J 'Promotion by the British Pharmaceutical Industry, 1983-8; A Critical Analysis of Self-Regulation' (1990) 300 BMJ 3.

¹⁴⁴Teff, H 'The Law and Ethics of Medical Experimentation' (1987) PN184.

doctors by offering them money and gifts to prescribe its heart drug Adalat Retard and for not disclosing adverse data. It has been argued that the threat of being reported to the Office of Fair Trading (OFT) to determine whether the law prohibiting the restriction, prevention or distortion of competition had been breached would be a greater deterrent than being reported to the APBI because of the greater risk of extensive adverse publicity and because the OFT is not a trade association specific to pharmaceuticals.¹⁴⁵

In 1994 it was alleged that a pharmaceutical company (Upjohn) had fraudulently withheld adverse data obtained from clinical trials. Central to the case was Protocol 321, a trial of Halcion which was carried out in healthy prisoners in a US jail in 1972. Professor Oswald had acted as an expert witness in US litigation against Upjohn; it was during this time that he discovered that side effects were underreported to the Federal Drugs Administration (FDA) in the United States. The manufacturers, together with one of its senior employees, sued the BBC and Professor Ian Oswald for libel in a Panorama television programme and an article in the *New York Times*.¹⁴⁶ Despite the fact that an irregularity was proven, Upjohn were awarded a total of £ 85 000 in libel damages; this, however, resulted from the method of publication in the popular media rather than from an absence of fault. These are by no means isolated cases as a recent article in the *Washington Post* indicates where results of research, which showed that a thyroid drug was no better than its competitors' cheap generic versions, were withheld for seven years at a cost of \$ 350 M a year to the American nation.¹⁴⁷

Generally speaking, both within and outwith the NHS, the experience on which the success of research ethics committees can be judged is limited by their short history. However, the death of Janet Wigley, an elderly cancer patient, who was entered into a

¹⁴⁵Teff, fn 144 above.

¹⁴⁶See Brahams, D 'Upjohn (Halcion) and libel actions' (1994) 343 *Lancet* 1422, 'Memo suggests Upjohn concealed Halcion effects' (1994) 308 *BMJ* 677. See *The Guardian*, September 10, 1986.

¹⁴⁷'Thyroid Drug Study Reveals Tug of War Over Privately Financed Research' *The Washington Post* April 16, 1997. Wise, J 'Research suppressed for seven years by drug company (1997) 314 *BMJ* 1145. See generally Friedman, P J 'Mistakes and Fraud in Medical Research' (1992) 20 *Law, Medicine & Health Care* 17.

trial without her knowledge but with the agreement of eleven research ethics committee serves as a reminder that the review process is not infallible - the research committees thought it inappropriate to seek informed consent from elderly patients who were, anyway, close to death.¹⁴⁸

1.7.3.3. THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986

Thus, despite the calls for reform from some quarters, the current position in the United Kingdom is that there is no legislation governing the regulation of medical research involving human subjects. We could call this the 'Man's best friend paradox'; as a result of the Animals (Scientific Procedures) Act 1986 animals are far better protected as research subjects than are human beings.¹⁴⁹ This is not to argue from a "speciesist" standpoint but illustrates the spirit of an animal loving nation which has traditionally donated more to animal welfare charities than any other, including those concerning child welfare.¹⁵⁰ Animal rights activists are now amongst the most violent protest organisations in the United Kingdom. The use of the human beings in medical research does not have the same political impact. Consequently, there is no compelling pressure on a government to legislate as to the latter. The current position in the United Kingdom can be seen as amounting to an abdication of direct responsibility by the Government in favour of departmental 'advice'.¹⁵¹

1.7.4. THE REGULATION OF MEDICAL RESEARCH IN GERMANY

The overall regulatory framework for medical research in Germany is provided by two articles of the Basic Law, the right to life and bodily integrity and the right to conduct

¹⁴⁸See Brazier, fn 127 above at 412 and Phillips, M and Dawson, J *Doctors' Dilemmas. Medical Ethics and Contemporary Science* (1985) at p. 63-64.

¹⁴⁹The use of animals in medical research has been controlled by law since 1876.

¹⁵⁰See the editorial by Richard Nicholson in (1995) 149 Bull Med Eth 1.

¹⁵¹This will be explored in Chapter Six.

research. The right to conduct research is provided by article 5 (3) of the Basic Law and states that,

“Art and scholarship, research and teaching shall be free. Freedom of teaching shall not absolve anybody from loyalty to the constitution.”¹⁵²

The State has a duty to ensure that financial and organisational measures are in place so that the right to research is uninhibited.¹⁵³ This duty is both objective and subjective. It is objective to the extent that the relationship between science, research and education and the state is normatively based. It is subjective inasmuch as an individual involved in research has a right to conduct research.¹⁵⁴ The state thereby not only undertakes not to interfere with the conduct of science but it also has to act in such a way as to safeguard the right. The emphasis of article 5 (3) is protective as between the medical researcher and the state and the medical researcher and university bodies.¹⁵⁵ This is amplified for doctors engaging in medical research by the right to a vocation as provided by article 12 of the Basic Law.¹⁵⁶

Generally speaking, article 5 (3) has been criticised for being vague in its terms.¹⁵⁷ A further conflict, which has been described as a collision,¹⁵⁸ arises between articles 5 (3) and 2 (2) of the Basic Law. The latter provides that,

“Everybody has the right to life and physical integrity. Personal freedom is inviolable. These rights may not be encroached upon save pursuant to a law.”¹⁵⁹

¹⁵²See in *The Basic Law for the Federal Republic of Germany* (Version in effect since 15 November 1994) at p. 15.

¹⁵³Von Münch I / Kunig P *Grundgesetz-Kommentar* (4th edn, 1992), Rn. 104 zu Art. 5 (3) GG. See also Stein, E *Staatsrecht* (14th edn, 1993).

¹⁵⁴BVerfGE 35, 79 [112ff.]-Nieders. VorschaltG.

¹⁵⁵OVG Berlin, JZ 1973, 210.

¹⁵⁶Article 12 (1) “All Germans have the right freely to choose their occupation or profession, their place of work, study or training. The practice of an occupation or profession may be regulated by or pursuant to a law.” See fn 152 above.

¹⁵⁷Von Münch / Kunig, fn 152 above at Rn. 116 zu Art. 5 (3) GG.

¹⁵⁸Classen, C D ‘Ethikkommissionen zur Beurteilung von Menschen am Menschen: Neuer Rahmen, neue Rolle’ MedR 1995 149.

¹⁵⁹Art. 2 Abs. 2 GG which is part of the Right to Liberty contained in Art 2. See fn 151 above.

Thus, it might be more appropriate to speak in terms of a balance rather than a conflict.¹⁶⁰ Article 2 (2) of the Basic Law emphasised the interests of the individual.¹⁶¹ Indeed, a particular characteristic of the German legal approach lies in its aim to uphold the right to self-determination.¹⁶² The underlying rationale is to be found in the history of the Third Reich which continues to underpin most, if not all, of the discussions concerning medical ethics.¹⁶³ For example, the position in Germany as regards randomised clinical trials (RCTs) as provided by the drugs code (AMG) is unequivocal - known effective treatment may never be withheld when a new drug is being tested.¹⁶⁴ The position in practice is that such research may be conducted under strict conditions but subjects must be told of the design of the trial when a placebo group is being used.¹⁶⁵ They do not, however, have to be told to which group they actually belong.

1.7.4.1. THE DEVELOPMENT OF RESEARCH ETHICS COMMITTEES IN GERMANY (*ETHIK-KOMMISSIONEN*)

Most of the *Ethik-Kommissionen* in Germany were established between 1979 and 1982. Although the declaration of Helsinki (1964) had alerted the medical profession to the need to introduce committee review, the impetus to set up such committees derived, in the main, from a recommendation from the German Research Community (*Deutsche Forschungsgemeinschaft*).¹⁶⁶ The legislature, however, continued to rely on its policy of

¹⁶⁰ "...the freedom of professions and of science are worthy of protection, making it a constant task to balance those rights with human dignity, the rights to life, physical integrity, and family protection." Riedel, E 'The Constitution and Scientific and Technical Progress' in Starck, R (ed) *New Challenges to the German Basic Law* (1991) at p. 85.

¹⁶¹ See Fischer, G *Medizinische Versuche am Menschen* (1979) p. 3.

¹⁶² "When the framers devoted the first nineteen articles of the Basic Law to guaranteed rights and liberties, they consciously set out to underscore the priority of individual freedom." Kommers, D P *The Constitutional Jurisprudence of the Federal Republic of Germany* (1989) at p. 245. See also fn 159 above at p. 16.

¹⁶³ See also the response to the treatment of cystic fibrosis by artificial insemination which was dismissed in Germany as an exercise in eugenics. See "Throwing Away ill Embryos?" (*Kranke Embryos wegwerfen?*). *Frankfurter Rundschau*, January 21, 1997 at p. 26. See also 'Embryo - Zerstörung ein Horror' *Frankfurter Rundschau* July 31, 1996 at p. 1. For an outline of the reactions to cloning see 'Germans on their high horse over cloned sheep' *The Guardian* March 6, 1997 at p. 11.

¹⁶⁴ See Liedtke *NJW* 1977 2133.

¹⁶⁵ See also fn 233 below.

¹⁶⁶ Comparable to the Medical Research Council in the United Kingdom.



leaving the regulation of medical research involving human subjects up to the self-regulation of the medical profession.¹⁶⁷ Accordingly, the move to impose tighter controls on research originated from within the medical profession.

1.7.4.1.1. Guidelines

On January 12, 1979 the German Federal Medical Convention recommended that state medical councils should provide for the establishment of ethics committees which would be responsible for advising researchers on ethical and legal issues of clinical research involving human subjects; this, however, was merely a recommendation¹⁶⁸ and not legally binding.¹⁶⁹ The Convention went on to include in its 1985 draft professional code that,

“The physician before conducting any clinical experiments involving humans, or research with vital human gametes or living embryonic tissue, or epidemiological research with person-related data, should call upon an ethics committee constituted by the medical council of the medical faculty to give advice about the professional ethical and legal questions associated with his or her project. The advice to be given to the physician should be based on the Declaration of the World Medical Assembly of 1964 (Helsinki) in its revision of 1975.”¹⁷⁰

In view of the independence of the regional or “land” medical chambers (*Landesärztekammern*) from the federal medical chamber (*Bundesärztekammer*), the 1985 recommendation was implemented differently throughout the regions.¹⁷¹ For example, in respect of submission of protocols to research ethics committees, the word “ought” was replaced by “must” in the regional guidelines of Bayern, Hessen, Niedersachsen, Nord-rhein, Westfalen-Lippe and Schleswig-Holstein.¹⁷²

¹⁶⁷Wiesling, U ‘Zur Geschichte der Ethik-Kommissionen in Deutschland’ in Ach, J S, Gaidt, A (eds) *Herausforderung der Bioethik* (1995) pp 235-241.

¹⁶⁸There were several issues which the German Medical Convention’s recommendation did not clarify one of which related to the composition of research ethics committees. See Chapter Six.

¹⁶⁹There is however legislation in the form of the German Drugs Code (Arts 40-42) which provides for the “protection of persons in a clinical trial” in relation to the development and introduction of new drugs; it does not however, include innovative surgical procedures.

¹⁷⁰Translation provided in Schlaudraff, fn 24 above at 42.

¹⁷¹Furthermore, it did not apply to the private Ethik-Kommissionen which had begun to emerge. See Chapter Six at Section 6.1.1.2.

¹⁷²See Wiesling, fn 167 above at 236.

An official working party, *Arbeitskreis medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland* was established in 1983 and was entrusted with overseeing the work of the *Ethik-Kommissionen* of the *Landesärztekammern*, the medical faculties and the National Department of Health (*Bundesgesundheitsamts*); private *Ethik-Kommissionen* were not included.¹⁷³ The working party developed yet more guidelines, together with a check list to be used when considering a research proposal, in an attempt to unify research practices.¹⁷⁴ The move towards the American concept of research ethics by committee was further shown by the establishment of specialised committees such as that for reproductive technology and embryo research, which was set up by the federal physicians's chamber (BAK).¹⁷⁵

Eventually, in 1988, the federal Convention replaced the word "should" in respect of the use of ethics committees in section 1 (4)¹⁷⁶ to a "must", the effect of which was to compel all doctors involved in clinical research on human subjects to submit research proposals to ethics committees and to abide by their decisions.¹⁷⁷ It will be noted that measures for reform originated from the periphery rather than being dictated from the centre.

The AMG was amended in August 1994 to provide that a clinical trial for a new drug may only commence once it has been approved by an independent *Ethik-Kommission*

¹⁷³See the distinction between public and private *Ethik-Kommissionen* in chapter seven.

¹⁷⁴They also included recommendations as to the number of members which committees should have together with proposals for their selection. See Wiesling, fn 167 above at 237.

¹⁷⁵Thus, in 1985, the *Zentrale Kommission zur Wahrung ethischer Grundsätze in der Reproduktionsmedizin, Forschung an menschlichen Embryonen und Gentherapie* controlled all research on human embryos until it was disbanded pursuant to the introduction of the code, the *Embryonenschutzgesetz* (1991) 13. 12. 1990 BGBl. I, 2746.

¹⁷⁶See fn 24 above at 42.

¹⁷⁷The section now reads as follows; "Der Arzt-gemeint ist der Arzt der einen klinischen Versuch zu verantworten beabsichtigt-muss sich vor dessen Durchführung von einer bei seiner zuständigen Landesärztekammer oder einer medizinischer Fakultät gebildeten Ethik-Kommissionen über die damit verbundenen berufsethischen und berufsrechtlichen Fragen beraten lassen." [own emphasis added].

established under state law.¹⁷⁸ It is now federal law that a researcher must seek the approval of a research ethics committee.¹⁷⁹

Whereas the AMG appears to be restrictive, it is, in effect, quite flexible - so flexible in fact that it has been referred to as "soft law".¹⁸⁰ Indeed, it is less restrictive than is the code which protects research involving animals¹⁸¹ or the codes which regulate biotechnology¹⁸² and the protection of embryos.¹⁸³ First, it does not apply to *freie Kommissionen* - or private committees - which remain exempt from regulation.¹⁸⁴ More importantly, however, the researcher can, technically speaking, still go ahead should the committee decline to approve the protocol. The final competence to adjudicate on the matter is retained by a supervisory body established at Federal level,¹⁸⁵ the *Bundesinstitut für Arzneimittel und Medizinprodukte* (BfArM). This is the final appellate division, so to speak, as the trial may only go ahead once the BfArM gives its approval. The supervisory body may authorise a research program even if the research committee did not give its approval. In these circumstances, the supervisory body has 60 days in which to give the final go ahead.¹⁸⁶

1.7.4.3. THE GERMAN DRUGS CODE (*ARZNEIMITTELGESETZ:AMG*)

Pharmacological research is strictly regulated in Germany. The AMG, which was first introduced in 1961, regulates all pharmaceutical experiments involving human and animal

¹⁷⁸5 Novelle des Arzneimittelgesetzes (AMG) vom 19. 10. 94 BGBl. 1994 I. 3018 ff. which implemented an EU guideline 91/507/EWG v. 19. 7. 91. See L 170/32.

¹⁷⁹See Classen, fn 158 above at 148 and also generally Sobota, K 'Die Ethik-Kommission - Ein neues Institut des Verwaltungsrechts' AöR (1996) 121, at p. 229.

¹⁸⁰See Sobota, fn 179 above at 234. See Appendix D for §§ 40 and 41 of the AMG. Author's translation included.

¹⁸¹See Tierschutzgesetz of 18. 8. 1986 BGBl. I, 1319.

¹⁸²Gesetz zur Regelung von Fragen der Gentechnik of 20.6.1990 BGBl. I, 1080.

¹⁸³Embryonenschutzgesetz, fn 175 above at 2746.

¹⁸⁴In May 1994, the German parliament attempted to amend the law to include private committees but the amendment failed because of the success of the representation of the States (*Bundesrat*) via the parliamentary arbitration committee. See (1994) 344 Lancet 398.

¹⁸⁵See § 67 AMG.

¹⁸⁶*Ibid.* para 3.

subjects conducted by doctors and dentists.¹⁸⁷ The introduction of the Code was catalysed from the commercial sector - the pharmaceutical industry itself¹⁸⁸ - rather than by way of an appeal to history. The stated aim of the AMG has always been to supervise the circulation of medications, ranging from how the products are distributed, tested, packaged and stored.¹⁸⁹ It implements the Good Clinical Practice Guidelines of the European Union.¹⁹⁰

The provisions of the AMG include the establishment of a compulsory insurance scheme financed by those responsible for the research - the advantage being that the cost of protection is spread amongst those with the deepest pockets. Moreover, research subjects are guaranteed a right to information. This right applies to the protocol only; it does not extend to the financing of the research¹⁹¹ or to other research being undertaken in the field. Thus, there is no database for ongoing research, a provision which is advocated later in this thesis. The German model goes some way towards eroding opacity which traditionally affects medical research. However, several questions remain unanswered. Is the medical research process in Germany really as transparent as it appears on paper? Is the influence of the past disproportionate? Is the German model too restrictive or prohibitive?

In effect, the AMG seeks to protect all human research subjects including volunteers and patients. The law is that it prescribes the nature and the scope of *clinical trials* by providing legally binding provisions. It does not apply to *innovative* treatment; thus, the trial must be a planned systematic study of a medicinal product.¹⁹² Moreover, research into surgical techniques is not regulated by the AMG which aims to provide research

¹⁸⁷See the provision for dentists at § 21 [22] (2) Nr. 3 AMG.

¹⁸⁸Hügel, H, Fischer, J, Kohm, B *Pharmazeutische Gesetzeskunde* (28th edn 1990) at p. 175 et seq.

¹⁸⁹¹⁸⁹See the 12th section of the AMG in §§ 64-69 AMG. And also Lippert, H D & Strobel, E-S 'Die Überwachung klinischer Prüfungen nach dem AMG' VersR 95, 637.

¹⁹⁰See fn 233 below.

¹⁹¹This might be of considerable interest to some subjects who would not wish to co-operate with companies whose ethics were suspect. See fn 146 above.

¹⁹²See § 64 Abs. 1. 2 AMG and §§ 40 ff AMG.

subjects with legal protection by way of imposing criminal liability in the event of non-compliance with the code.¹⁹³

(a). Therapeutic and Non-Therapeutic Research

The AMG distinguishes between therapeutic (§ 41) and non-therapeutic (§40) research. In respect of the former, the medication to be used must have a therapeutic effect which must be proved by reference to current medical knowledge.¹⁹⁴ Essentially, § 41 provides that such research is permissible if the patient's symptoms are such that a new medication is likely to have a positive effect and will also contribute to research. The test has two limbs. First, the positive effect must be judged in relation to a patient in a similar position ("*in seine Lage*"), the 'reasonable patient'. A subjective strand is introduced by way of the reference to the illness and the way in which it affects that particular patient (*individuelle Krankheitsbild*).

Regulations for non-therapeutic research rely on the same tests save, of course, that there is no requirement for a therapeutic effect.

(b). The Design of the Trial

A trial involving human subjects may only proceed when sufficient pharmacological and toxicological trials have been carried out on animals.¹⁹⁵ Furthermore, the physician

¹⁹³§ 38 AMG.

¹⁹⁴The exception being at the early stages of the trial. This would include, say, the testing of antidotes of cancer drugs which could not permissibly be tested on healthy volunteers.

¹⁹⁵§ 40 (5) AMG.

conducting the trial must have a minimum of two years of practical experience in this area.¹⁹⁶ This applies to both therapeutic and to non-therapeutic research.

As in the United Kingdom, there are four phases of a clinical trial. Phase I involves in the region of 10-50 subjects and comprises the first tests after those carried out on animals; these are usually in the form of dose finding studies (*Verträglichkeit der Substanz*). Phase II usually takes place in hospitals and may involve controlled clinical trials (RCTs) with up to 200 research subjects. Phase III is conducted in either a clinic or a medical practice, and often includes multicentre trials and other observational experiments¹⁹⁷; the number of research subjects may reach the figure of 1000. Lastly, phase IV is in the form of controlled studies - including blind or double blind trials.¹⁹⁸

The protective emphasis of the Code is illustrated by phases I-III of a trial which are covered by a no-fault liability provision as contained in § 823 of the Civil Code (BGB)¹⁹⁹ and the duty to provide insurance in § 94 of the AMG. The pharmaceutical company which markets that particular drug is criminally liable in the event of harm. The company will also be liable for the damages which results from altering the product during the trial.²⁰⁰

(c) The Risk / Benefit Analysis

¹⁹⁶§ 40 (1) Nr 4 AMG.

¹⁹⁷These trials are designed to test for side effects as well as to ascertain therapeutic value.

¹⁹⁸The distinction is the same throughout the world; the research subjects in a blind trial are not told whether they are in the placebo group. In a double blind trial, the doctors also do not know.

¹⁹⁹See § 84 AMG.

²⁰⁰This is carried out in accordance with the principle of *nihil nocere*. See § 84 AMG and also § 823 of the Civil Code

A clinical trial may only go ahead if the risks involved are justified by the possible benefit.²⁰¹ The researcher is responsible for the weighing up of interests, (*Güterabwägung*), before and during the trial. Controversially, it is the decision of the researcher, rather than of the clinician in charge of the patients, to decide whether the trial is justified in the expectation of significant danger.²⁰² It is important to note that the only opportunity for the risk / benefit analysis to be appraised outside the mind of a researcher is during the deliberations of research ethics committees. In neither circumstance do openness, or public accountability, feature prominently.

(d). Consent

The subjects must understand the nature, the meaning and the effect of the clinical trial with particular reference to the possible risks involved (*"...Wesen, Bedeutung und Tragweite der klinischen Prüfung, insbesondere über die mit ihr verbundenen Risiken..."*).²⁰³ Only then, can consent be described as being free and informed. Case law has interpreted the conditions for obtaining consent as including full and frank disclosure,²⁰⁴ as regards innovative or experimental therapy, the more untested the method is, the more stringent the duty is for informed consent.²⁰⁵ The commentary (*Kommentar*) for the AMG states that informed consent must be full and frank, especially as regards non-therapeutic research, and that the risks must be fully explained to the research subject.²⁰⁶

(e). Research Subjects

²⁰¹See the Kohlhammer *AMG Kommentar* (1996) at p. 13 and also § 38 (40) (1) Nr 1.

²⁰²This is of course at a primary level as the research ethics committee becomes involved at a secondary level.

²⁰³§ 40 (1) Nr 1 (2) AMG.

²⁰⁴BGHZ 20, 61 [65] 'Thorotrast'.

²⁰⁵See for example 'Wenn Ärzte pfuschen' Interview with Professor Dr. Dieter Giesen in *Die Zeit* September 3, 1993.

²⁰⁶Kohlhammer, fn 201 above at 17.

Research on children and the mentally incapacitated is strictly forbidden with the exception of therapeutic research which is permitted in exceptional circumstances. To this extent, the AMG is a product of its historical context²⁰⁷ in seeking to protect those who are particularly vulnerable. This position can be contrasted with the more flexible position in the United Kingdom.

(I) Children

It is permissible to involve children in diagnostic research and research into preventive medicine (*Vorbeugungsmittel*).²⁰⁸ Children should not be used if the product can be tested on adults; they are, thereby, afforded special protection. Written as well as verbal consent must be obtained by a legal guardian, who can be the child's parents²⁰⁹ or a guardian entrusted to look after the child. It is important that the child has a sufficient understanding and ability to form a judgment (*Verständnis und Urteilsvermögen*) - a condition which can be assumed in a minor of 16 years or over.²¹⁰

(ii) Mentally Incapacitated

Clinical research may be carried out on those who are incapable of giving effective consent (*Geschäftsunfähig*) which includes those who are mentally handicapped. However, such research may only be carried out if an individual can form an understanding of the broad nature of the procedure involved (*Lage, Wesen, Bedeutung und Tragweite*). Further protection is provided by the stipulation that he or she may only become a research subject with the agreement of his legal guardian or care assistant.

(f). Insurance

²⁰⁷ See fn 188 above.

²⁰⁸ § 41 (4) Nr 2 AMG.

²⁰⁹ § 1626 (2) of the Civil Code (BGB).

²¹⁰ See the Kohlhammer, fn 201 above at 25. The point of comparison in the United Kingdom is *Gillick v. West Norfolk and Wisbech Area Health Authority* [1986] AC 112, [1985] 3 All ER 402, HL.

The insurance provision in the German Drugs Code is innovative. In effect, it spreads the cost of protection to those who can afford the substantial premiums. According to paragraph 40 (1) Nr 8, a clinical trial of a new medication involving human subjects may only proceed once an insurance scheme has been set up enabling research subjects or their dependants to be compensated in the event of physical harm or death resulting from the trial. The scheme must be based on a contract of insurance thus absolving the research subject from the need to prove fault. A causal link must, however, be shown between the injury or the death and the participation in the trial.²¹¹ The nature of the agreement is that of a third party insurance contract which enables the research subject to seek a claim from the insurance company.²¹² Recourse to the scheme is activated if no other party will pay for the damage.²¹³ Paragraph 41 AMG further provides that this scheme also applies to innovative treatment (*Heilversuche*).²¹⁴ The scheme must total at least 500, 000 DM.²¹⁵ Legal sanctions may be invoked if such a scheme is not set up. Paragraph 823 (2) of the Civil Code (BGB) provides that those responsible for running the trial, including the doctor, may be liable to pay damages according to the principles of delict.²¹⁶

²¹¹See Kohlhammer, fn 200 above at 23-24. It was held in a special hearing (*Sachverständigenanhörung*) by the *Bundesaufsichtsamt für das Versicherungswesen* (National Supervisory Body for Insurance) on October 11 1977 and by the *Bundesfinanzministerium* (the Treasury) on October 17, 1977 that the Insurance company may pay even if the claim under delict against those who are responsible for the conduct of the trial of the doctor is not sustainable.

²¹²“...es handelt sich um einen (Versicherungs) Vertrag zugunsten Dritter, da der Proband oder Patient einen unmittelbaren Anspruch gegen den Versicherer erhält.” See Kohlhammer, fn 201 above at 24. The contract must also conform with § 2 VAG and there are further guidelines which are published by the *Bundesverband der Pharmazeutischen Industrie und dem Verband der Haftpflicht-, Unfall- und Kraftverkehrs-Versicherer* ‘Allgemeine Bedingungen für die Versicherung der klinischen Prüfung von Arzneimitteln (Probandenversicherung)’ See Kohlhammer, fn 201 above at appendix II. (Comparable to the APBI guidelines in the United Kingdom).

²¹³Many pharmaceutical companies for example have their own no-fault compensation schemes.

²¹⁴Namely, where the research subject is a patient. See the distinction drawn above between § 40 and § 41 AMG.

²¹⁵§ 40 (1). Nr 8 AMG. This must be in the form of accident insurance (*Unfallversicherung*) or insurance against damage (*Schadenversicherung*).²¹⁵ If the risks are particularly high, those financing the trial must insure accordingly, even if the premium extends beyond 500, 000 DM. If the high degree of risk was foreseeable and a company failed to insure as such, it is liable under § 823 (2) of the Civil Code as well as under § 40 (1) Nr 8 and Abs 3 AMG.

²¹⁶See Kohlhammer, fn 201 above at 23.

(g). A Right to Information

Research subjects have a right to information²¹⁷ and it is the duty of the doctor to provide them with information regarding the insurance provisions of the experiment.²¹⁸ It is suggested that this duty could be extended. For example, a regrettable omission is that the same duty does not apply to those responsible for funding the research. Furthermore, the right could be extended to researchers by providing them with a database detailing ongoing medical research. This would be particularly useful as a way of avoiding unnecessary duplication of research results.

(h). Sanctions for Breach of Paras 40 and 41

The protective nature of the Code is amplified by the strict sanctions which may be invoked in the event of non-compliance with the provisions. If a researcher violates the code in any way, he may be liable for a prison sentence of up to one year or a fine of up to 50, 000 DM.²¹⁹ The Code thereby emphasises the researcher's responsibility, particularly as regards his duty to weigh up the risks of the proposed research. The director of the premises where the doctor carried out the research may also be held liable in view of his position of responsibility.

Despite the strict regulation of the research involving human subjects, the position in Germany is similar to that in the United Kingdom and the United States to the extent that research is regulated by committees which derive their conceptual and their 'legal' basis from guidelines drawn up by the medical profession, the revised declaration of Helsinki.

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²¹⁷ As well as that relating to informed consent. See above.

²¹⁸ Laufs A & Uhlenbruck W, *Handbuch des Arztrechts* (1992) § 130, 35.

²¹⁹ See § 96 Nr 10 AMG which applies to Nrs 1 - 5, 8 of § 41 Nr 1 and (4) of § 97 (1) Nrs 6 and 7 for § 41 AMG which provides for sanctions by way of *Bußgeldvorschriften*. It is of interest to note that this is not an instrument of criminal law (*Strafrecht*) but that it is a public order offence (*Ordnungswidrigkeit*).

²²⁰ See Wiesling, fn 167 above at 228.

1.8. INTERNATIONAL GUIDELINES: THE DECLARATION OF HELSINKI (1964) ²²¹

International guidelines were drawn up by the World Medical Association in 1964 in the form of the Declaration of Helsinki. The informed consent requirement was gradually displaced from the pole position it occupied in the Nuremberg Code. However, the declaration of Helsinki provided an altogether new element in the form of the submitting of research proposals for committee review.

Paragraph III 3 a ²²² provides that,

“The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specifically appointed independent committee for consideration, comments, and guidance.” ²²³

This has since been extended in the declaration of Helsinki in Hong Kong in September 1989 which further provides that experimental protocols ought to be transmitted for consideration, comment and guidance to a,

“...specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.” ²²⁴

The guidelines illustrate the international community's concern as regards unethical research; they represent a form of international control, even though the ambit of that control is limited. The national controls in the United Kingdom, Germany and the United States are based on these guidelines. One might ask whether they represent a vehicle for the emotions and the aspirations of the international community, or are they

²²¹ Also in its revised forms.

²²² And subsequently para I 9 of the revised declaration of Tokyo 1975.

²²³ [1.2] An additional form of protection is provided by Principle I.8 which stipulates that the results of research conducted in violation of Helsinki's requirements ought not to be published.

²²⁴ See Klingmann, I, Kori-Lindner, C and Witte, P U *Ethik in der Klinischen Prüfung; Ethik Kommissionen-Funktion und Arbeitsweise* (1991) at p. 191.

simply, "...a restatement of the aims of medicine... supplement[ing] the doctor's ethical commitments as expressed in the Hippocratic Oath."?"²²⁵

1.8.1. STATUS OF THE INTERNATIONAL GUIDELINES

The prevailing presumption is that international guidelines provide a legitimate basis on which to establish legal authority.²²⁶ This argument is, however, of limited applicability as it assumes that the dilemmas surrounding the regulation of medical research involving human subjects are to be resolved from within the medical community alone.²²⁷ Furthermore, sole reliance on international guidelines assumes that international codes relating to such a specific area express all the relevant principles and rules.²²⁸

International guidelines, such as the Declaration of Helsinki provide only part of the theoretical framework for human experimentation as opposed to a complete basis for control;

"...the device of international agreements and commitments can provide only the theoretical framework which may assist medicine in its search for a philosophical basis for overall assessment of its aims and practices. At a more practical level, however, it cannot achieve rational control of experiments. This is so not simply because of the lack of sanctions which can be applied in the event of breach of any such agreements, but also because they are stated in a general rather than a specific way."²²⁹

²²⁵McLean, S and Maher, G, *Medicine, Morals and the Law* (1983) at p. 104. [own emphasis].

²²⁶"At regional level and international levels, professional bodies have adopted ethical guidelines intended to reflect regional or universal values and which embody an ethical consensus. They therefore have a powerful moral force if not legal enforceability." British Medical Association, *Medicine Betrayed: The Participation of Doctors in Human Rights Abuses* (Report of a Working Party 1992) at p. 12.

²²⁷Wiesling, fn 167 above at 240.

²²⁸"Professional codes are beneficial if they effectively incorporate defensible moral principles and rules in the relationship they govern. Unfortunately, some professional codes oversimplify moral requirements or claim more completeness and authority than they are entitled to claim. As a consequence, professionals may suppose that they have satisfied all moral requirements if they have obediently followed the rules of the code, just as many people believe that they have discharged all their obligations when they have met the relevant legal requirements." See Beauchamp, T L and Childress, J F *Principles of Biomedical Ethics* (1989) at p. 12.

²²⁹McLean and Maher, fn 225 at 106.

The benefit of guidelines is that they form the base on which legislation is founded - and this is borne out by the regulatory models in the United Kingdom and in Germany.²³⁰

These national controls have been criticised for being dominated by the medical profession, whose opinions, certainly in the United Kingdom, continue to govern the standard by which physicians are judged.²³¹ The Declaration of Helsinki deals with issues which lie close to the heart of the medical profession. Moreover, the bulk of the way in which research is controlled is left up to the conscience of the researcher. This will be discussed in detail in Chapter Four dealing with moral reasoning in the medical research debate. The emphasis on the researcher's conscience has been followed by subsequent guidelines for research.

1.9. EUROPEAN GUIDELINES: GOOD CLINICAL PRACTICE (GCP)

According to an European Community Directive, all phases of clinical investigations must be undertaken "in accordance with good clinical practice"²³² which is defined in the Good Clinical Practice Guidelines.²³³ Whereas the GCP does involve some important provisions for the protection of the rights of human subjects involved in research they should also be seen as a set of management procedures devised to prevent mistakes and fraud. The GCP incorporate important ethical principles such as the patient's informed consent to experimental procedures and overview by a research ethics committee.

²³⁰Though arguably not in the United States, who were not represented at the Helsinki conference.

²³¹"This means that such controls as do exist may serve to reflect a purely, or substantially, medical view of the aims and morality of experiments with little weight attached to the competing claims of community based morality or perceptions." McLean and Maher, fn 225 above at 113.

²³²91/507/EEC. The United Kingdom has implemented the EC directive through the Medicines (Applications for Grant of Product Licences - Products for Human Use) Regulations SI 1993 No. 2538 which provides that all phases of clinical investigations must be undertaken "in accordance with good clinical practice".

²³³Notes for Guidance on Good Clinical Practice for Trials on Medicinal Products in The European Community (EC) 1990 III / 3976 / 88 - EN. [Approved July 1990; effective July 1991]. Also published in *Pharmacology & Toxicology* (1990) 67 at pp. 361-372.

The GCP marks a great step forward and should reduce the piecemeal development in which trials are conducted in member states of the European Union. The essence of the GCP is the complete verification of data. Thus, for example, there is monitoring of the study throughout by the sponsor and there is an audit of investigator's systems and records are made by a Quality Assurance (QA) unit independent of the company Medical Department which also performs some repeat checks. There may also be a further inspection and audit on behalf of governmental regulatory authorities. At the heart of the provisions is the passage of information;

"Information should be given in both oral and written form wherever possible. No subject should be obliged to participate in the trial. Subjects, their relatives, guardians, or if necessary, legal representatives must be given ample opportunity to enquire about details of the trial. The information must make clear that refusal to participate or withdrawal from the trial at any stage is without any disadvantage for the subject's subsequent care. Subjects must be allowed enough time to decide whether or not they wish to participate."²³⁴

The legal requirement applies to both the public and private sector when developing data for submission to any European Regulatory Agency²³⁵ in support of a new product. Further guidelines have been issued by the Council of Europe in the form of the Convention on Human Rights and Biomedicine, Chapter V, arts. 15 - 18.²³⁶ The Convention, however, as still to be ratified by both the United Kingdom and Germany.²³⁷

1.10. CONCLUSION

²³⁴1.9 GCP (1990), fn 233 above.

²³⁵As, for example, the European Agency for the Evaluation of Medicinal Products (set up by the European Council) through Council Regulation No. 2309 / 93 of July 22, 1993. OJ 24 / 8 / 93, L 214 pp. 1-21.

²³⁶DIR/ JUR (96) 14.

²³⁷See *Das Parlament*, July 18.25, 1997 at p. 13.

It would be incorrect to say that questions as regards medical research are not being asked. Rather, these questions are being posed but within spheres which are private and virtually impenetrable by the public sphere. This is a drawback of using committees as the main model of controlling research as questions raised by medical research are being intellectualised within professionalised closed groups.

The professional élite both in Germany and the United States played a vital role in upholding the justification for conducting certain forms of research. The German legal system, for example, was not a victim of national socialism but was an accomplice; both lawyers and judges actively promoted the ideology of national socialism.²³⁸ The same can also be said of some American judges during the height of the Cold War.²³⁹ As regards medical research, the professions retain most of the responsibility for controlling research. They should, in my opinion, continue to do so. The trust we vest in them, however, must be qualified. First, their role in the regulation of medical research must be clarified. Secondly, the public have a right to be represented, through Citizens' Juries or otherwise. This is addressed in the next two sections.

²³⁸Müller, I *Furchtbare Juristen* (1989) and also Rottleuthner, H 'Substantieller Dezionismus zur Funktion der Rechtsphilosophie im Nationalsozialismus' (1983) *Arch Rechts-und Sozialph/Beiheft* 18, 20.

²³⁹See above.

SECTION TWO: METHOD

THE MEDICAL RESEARCH DEBATE: IN SEARCH OF PRINCIPLES

CHAPTER TWO

MEDICAL RESEARCH AND SCIENTIFIC REASONING : DEFINITIONS AND RISKS

"These terms, nevertheless, are beset with numerous ambiguities: their meaning, instead of being simple, is extremely complex: and every debate which embraces Law as a whole, should point distinctly at those ambiguities, and should sever that complex meaning into the simpler notions which compose it. Many of those who have written upon Law, have defined these expressions. But most of their definitions are so constructed that, instead of shedding light upon the thing defined, they involve it in thicker obscurity. In most attempts to define the terms in question, there is all the pedantry without the reality of logic: the form and husk, without the substance. The pretended definitions are purely circular: turning upon the very expressions which they affect to elucidate, or upon expressions which are exactly equivalent."

John Austin¹

INTRODUCTION

The essential question in medical research - and, perhaps, the central pivot of this thesis - is how, and by whom, the underlying normative principles should be defined. There are three main protagonists in the field - the research workers themselves, the research subjects and the general public who are, at the moment, objective observers but who may, at any time, be required in a subjective role.

The expertise of the medical scientists is paramount within these groups. Their understanding of a given project must be far above that of the others and this gives them the 'God's eye vantage'. The danger of such a vantage point is that it can be used as one from which to view the scene as a whole despite the relatively narrow base on which the observer stands. To allocate the solution of the many social and moral questions

¹in Campbell, R (ed) *Lectures on Jurisprudence or the Philosophy of positive law* Vol II (5th edn, 1885) at p. 1075.

raised by research to the scientists is potentially dangerous in that they will be resolved by the select few whose expertise is, in fact, limited to the understanding of the scientific merits.

If society is to play a role in ascertaining the principles for research, it must learn to come to terms with and accept the scientific premises behind medical research.² Scientific reasoning must also, however, learn to come to terms with the down to earth attitudes of society. Symbiosis, rather than parasitism - in which one group gains at the expense of the other - must be an integral characteristic of the relationship. Only an informed public can contribute usefully to the medical research debate and, to this end, acceptable definitions are vital to public understanding of the issues. The public can give rational answers to the questions raised by research only if it understands them; and it is only if it understands them that it can contribute usefully to the political debate.³

We have, then, something of an ethical schism. The scientists, spurred on by the statisticians with their probability tests, are concerned to demonstrate the validity of a scientific hypothesis. They can, then, easily forget that they are using human subjects because the same human subjects have now been reduced to case numbers - and this attitude was imported into medicine itself with the introduction of laboratory-based medicine in the nineteenth century.

²This has been also argued by Professor Sheila McLean in relation to the Human Genome Project. See McLean, S A M 'Law, Ethics and the Human Genome Project' (1994, Edinburgh: Society of Solicitors in the Supreme Courts of Scotland Biennial Lecture) at p. 7.

³A concept which lies at the heart of Habermas' theory of discursive democracy which is based on the principle of universality. In essence, he argues that consensus can be achieved through communication. Real dialogue, however, is dependent on democratic structures which enable a consensus to be achieved in the light of the public sphere. See *Between Facts and Norms: Contributions to a Debate Theory of Law and Democracy* (1996, Rehg, W (tr)) at p. 359. I am indebted to Dr Gerard Delanty whose paper, 'New Conceptions of Radical Democracy: Habermas on Social Protest, The Public Sphere and the Law' given at the Centre for Law & Society, Faculty of Law Edinburgh University on November 28, 1997 helped me to further my understanding of Habermas.

Research subjects are, however, autonomous human beings⁴ and it was, particularly, the disregard of this fact which made Nazi concentration camp experiments,⁵ *Tuskegee* and *Hyman* so repellent. The search for scientific accuracy and statistical significance cannot go uncontrolled without consideration for the research subject's human dignity. It is at this point that public supervision - or the expressed wishes of the research subjects themselves - must exert its influence on the understanding that modern medicine, as we know it, cannot progress in the absence of modern medical research.⁶

2.1. THE IMPORTANCE OF TERMINOLOGY

A major development of intellectual thought during the twentieth century must certainly be the growing awareness of the power of language.⁷ Resorting to definitions, does not signify a move towards 'arid semantic debate'⁸ but it acknowledges the role of language as a tool; it is an instrument which we shape for our own purposes.⁹

The distinction between the various forms of research define the extent of the risks to which individuals are allowed to subject themselves. The art of definition has direct implications as regards to what a patient will consent and as to what the researcher's peers will accept. Research ethics committees are charged with the duty of assessing the risk / benefit analysis and whether the calculus points towards the worth of the

⁴"Scientific method provides for experiments conducted on models. Medicine, however, experiments not on models but on the subjects themselves." Illich, *I Limits to Medicine. Medical Nemesis: The Expropriation of Health* (1977) at 254. See also p. 225

⁵A lesson learned from Alexander Mitscherlich's book, *Das Diktat der Menschenverachtung* (1947) in which the documentation exhibited at the Nuremberg trial is characterised by the invisibility of the research subjects. It was easy to forget, for example, that the 'VPs' (*Versuchspersonen*) referred to in the letters cited by Mitscherlich were in fact humans. See Chapter One above at section 1.4.4.

⁶See Habermas on the role of the public sphere as a warning system. Fn 3 above at 359.

⁷Cf Hacking, *I Why does Language Matter to Philosophy ?* (1975).

⁸per Lord Bridge in *Re B* [1987] 2 WLR 1213, 1217 albeit in another context.

⁹See Orwell, *G The Penguin Essays of George Orwell* (1994) at 348.

objective. Definitions provide a key which enables a committee to unlock the mystery of how to assess the ethical and the legal validity of a research proposal.

In the case of medical research, ideas and concepts are expressed which cannot be easily understood by those without the necessary expertise. As a result, these experts have considerable power. Consider the power exercised by someone who explains but whom you can not understand. Consider also the way in which language can be used to influence people. The ability to define an illness gives people power. This power influences the way we perceive illness as well as those who are affected by it. An illness which is defined has a name which accords it recognition and legitimacy. This means that people with recognised symptoms are not automatically dismissed as malingerers.¹⁰ There are also consequences for medical research; it is at least unlikely that research into a 'pseudo illness' would be funded.

Be that as it may, definitions used in medical research are derived from the terminology used in standard scientific enquiry.

2.2. SCIENCE

Scientia, meaning knowledge, is at the origin of the word 'science'.¹¹ It refers to the activity of controlled or designed observations based on a specific plan. Scientific reasoning has traditionally been defined as being based on ordered, deductive thought as opposed to inductive knowledge acquired through belief or hearsay.¹² The implication is that scientists deal with the hard currency of facts as opposed to the loose change of opinions. The word "science" carries considerable weight; it has an aura bordering on the mystic. Moreover, it encourages people to believe that science is absolute;

¹⁰Consider the controversy surrounding, *inter alia*, myelo encephalopathy (ME) or pre-menstrual tension.

¹¹This is cited as its primary definition in the *Concise Oxford Dictionary* (7th edn, 1982).

¹²See Medawar, P *The Limits of Science* (1986) at p. 3. See also Gee, D J and Mason, J K *The Courts and the Doctor* (1990) at p. 87 et seq.

"There is an abundance of evidence from every day life that science is held in high regard, in spite of some disenchantment with science because of consequences for which some hold it responsible, such as the hydrogen bombs and pollution. Advertisements frequently assert that a particular product has been scientifically shown to be whiter, more potent, more sexually appealing or in some way preferable to rival products. By doing so, they hope to imply that their claim is particularly well-founded and perhaps beyond dispute. In a similar vein, a recent newspaper advertisement advocating Christian Science was headed, "Science speaks and says the Christian Bible is provedly true", and went on to tell us that "even scientists themselves believe it these days".¹³

'Scientific' medicine increasingly impinges on all aspects of life in the western world and has become the yellow brick road to immortality. We want to live forever and expect the medical profession to deliver¹⁴ in what has been termed by some as the 'war on death'.¹⁵ The importance of primary medicine or preventative medicine is undervalued in a culture which increasingly resorts to curative solutions to illness. Writing about the treatment of diabetes, cancer or heart disease, Ulrich Beck argues that,

"These illnesses could be fought where they originate: by reducing the stresses of work or the pollution of the environment, or through a healthy way of life and a nutritious diet. Or the symptoms can be alleviated through chemical preparations. The different schools of fighting illness do not of course exclude one another, but one cannot actually speak of a cure through the second method. Nonetheless, we have so far generally opted for the medical and chemical 'solution'".¹⁶

Many improvements in health care have been effected by primary measures such as better sanitation, water purification, and education;

"To this extent experimentation on human subjects may be the result of the predominance of the marketing interests of these companies whose profit margins have shown them to have a fine business sense and a considerable control over the prescribing habits of doctors. Thus, the need for certain types of human experimentation is the result of the interests of drug companies in producing new products will be both useful and profitable."¹⁷

¹³Chalmers, A F *What is this thing called Science ?* (2nd edn, 1982) p. xv.

¹⁴"The general public has been led to expect too much from curative medicine and from medical progress." Giesen, D *International Medical Malpractice Law* (1988) at 704.

¹⁵Herman, J 'The ethics of prevention: old twists and new' (1996) 46 Br J Gen Pract 547 and also Cairns, J 'The Costs of Prevention' (1995) 311 BMJ 1520.

¹⁶Beck, U *The Risk Society: Towards a New Modernity* (1992, Ritter, M (tr)) at p. 176.

¹⁷McLean, S and Maher, G *Medicine, Morals and the Law* (1981) at 108.

The pharmaceutical industry has vested interests in the secondary problems and is able to present its case selectively.¹⁸ In acting for the good of society, it has the perfect cover to safeguard its own interests. The “contented and comfortable” not only enjoy the product of personal virtue, intelligence and effort¹⁹ but are able to live off society’s fixation with treatment as opposed to prevention.

Treatment is simple, it removes responsibility and provides a short term remedy whilst prevention necessitates self-discipline and continuing dedication to the task. If we take AIDS as an example, millions of pounds have been spent on research which has proved fruitless from the point of therapy. Nonetheless, the threatened pandemic has been contained by a combination of public education and responsible behaviour.²⁰

The true scientist seeks the truth - we might, however, echo Pontius Pilate in asking ‘what is truth?’ The scientific researcher will answer: ‘that which is shown to be true by way of scientific reasoning.’²¹ In discussing the basis of preference, Berlin has written:

“All these schools of thought, differing and indeed sharply opposed as they may be on many other crucial issues of principle, have at least one thing in common: they clearly favour one type of proposition or statement before all others; they treat it as possessing a virtue which other types conspicuously lack.”²²

Berlin was concerned specifically with schools of philosophical thought.²³ The same concepts, however, can be applied to medical research given the tensions between the

¹⁸Ibid.

¹⁹Term coined by Galbraith, J K *The Culture of Contentment* (1995) at p.18. The emphasis of his theory is that certain groups, the “contented”, monopolise and influence the political franchise in order to ensure that their interests are safeguarded. See p. 18.

²⁰See the Communication from the Commission to the Council and the European Parliament ‘Aids Policy of the Community and the Member States in the Developing World’ COM (93) 479 final at p. 4. And also Institut pour la Coopération Médicale (IMC) *Evaluation du Programme de Lutte contre le Sida de la CCE: Rapport Final* (1992). Biomedical and Health Research Programme (BIOMED 1) ‘AIDS: Ethics, Justice and European Policy’ (The Commission of the European Communities, Directorate General XII 1995).

²¹Or as Medawar refers to it, the preference of deduction over induction. Medawar, fn 12 above at 16.

²²Berlin, I *Concepts and Categories: Philosophical Essays* (1980) at 57.

²³He goes on to give examples of ‘good’ propositions and how each school of thought verifies them. “The selected ideal model of what a ‘good’ proposition should be will naturally differ according to the philosophical outlook of the logician and his school: Cartesians, after a formal bow to theology and ethics, inclined to place those of mathematics and mathematical physics fore most; Locke, Berkeley,

parties involved which the subject generates. Essentially speaking, the professionals - that is to say, lawyers, researchers, philosophers - in the medical research debate are in a continuous fight for legitimacy; it is a territorial 'tug of war' or a battle for 'turf';

"The difference between the 'unenlightened mob' and 'enlightened citizens' or, in more modern terms, between lay people and experts, shrivels and transforms itself into competition between different experts. In practically all social subsystems the internalization of norms and values is replaced by reflection in the light of competing components of systematic knowledge."²⁴

Medical researchers appear to claim a right to dominate the debate, by virtue of their knowledge. The implication follows that only those who possess this right can be responsible for the underlying principles of practice.

Consider, for example a response by a prominent physician, Baum to an article written by a lay person, Mrs Thornton, concerning consent and randomised controlled clinical trials in breast cancer.²⁵ He states that,

"Most of the lay public and sadly many of our political leaders have never been exposed to the open windows of science and thus have never been shaken out of their complacent beliefs in the myths of received wisdom."

And further,

"I share Mrs Thorntons's view that most consent within clinical trials conducted in the politically correct manner is ill-informed consent, yet until now few have had the courage to state this in public. In this respect, Mrs Thornton and I are allies but our responses to this challenge are diametrically opposed, which is no surprise as we emerge from two distinct cultures of our society, with differing backgrounds in the liberal arts and the biological sciences. Mrs Thornton's response is a plea for less science and a more open and honest dialogue with our

Hume, Mill, Russell, and modern empiricists pursue the ideal of empirical propositions, purified of everything which could make them erroneous, as being alone immediate, incorrigible, and simple, and for this reason 'fundamental'" Berlin, fn 22 above at 59.

²⁴See Bonß, W and Hartmann, H 'Konstruierte Gesellschaft , rationale Deutung. Zum Wirklichkeitscharakter soziologischer Diskurse' in Bonß, W and Hartmann, H (eds) *Entzauberte Wissenschaft. Zur Relativität und Geltung soziologischer Forschung* (Special Issue 3 of *Soziale Welt* 1985) p. 16. Translation reproduced in Beck, fn 16 above at 168.

²⁵Thornton, H 'Clinical Trials - a brave new partnership ?' (1994) 20 J Med Eth 19.

partners (the patients) in our search for better treatments for patients with cancer.”²⁶

By referring to “two distinct cultures”, Baum is in effect pulling rank on Mrs Thornton.²⁷ Implicit in this superiority is the assumption that only those who are party to scientific rationality may criticise it. Thus, science retains the exclusive capacity to criticise its own reasoning. Consider, for example, critical scientific traditions such as the theories of Karl Popper²⁸ and Thomas Kuhn.²⁹ Both have a characteristic in common, namely, that resistance to scientific hypotheses may be exercised by those within the scientific domain - almost like reserving the right to criticise one’s own family whilst resisting criticisms offered by others.

Karl Popper’s principle of falsification, for example, characterises the logic of science. It is a form of critical rationalism which maintains that science must be methodically self-critical because it is constrained by the fact that the pursuit of knowledge can never be completed as it is forever open to falsification. The key feature of Kuhn’s theory is the revolutionary character of scientific progress. A revolution involves the abandonment of one theoretical structure in favour of another. Hence, there is no ‘grand design’ accompanying the development of science; instead, it develops by piecemeal engineering through paradigm shifts. Both theories operate through the application of fallibility. It is arguable that they cancel themselves out to the extent that the continued application of scientific research often contradicts what was once claimed to be the truth.³⁰

More importantly, both critiques operate within the scientific community³¹ with the consequence that the scientific community is both a participant and a legitimating agency for establishing the objective criteria for its practice. Not only is access to self-criticism

²⁶Baum, M ‘Clinical Trials - A brave new partnership: a response to Mrs Thornton’ (1994) 20 J Med Eth 23 - 25.

²⁷One is reminded of Beck’s reference to “primary scientization” in which scientists rely on superiority by virtue of their claims to scientific rationality. Beck, fn 16 above at 158.

²⁸Popper, K *The Logic of Scientific Discovery* (1972).

²⁹Kuhn, T *The Structure of Scientific Revolutions* (1970).

³⁰Beck, fn 16 above at 36 - 38.

³¹Kuhn, fn 29 above at 66 et seq.

denied to those who do not have the necessary scientific expertise but science is not compelled to enter into a critical, reflective relationship with the object of its research - human beings. Scientists are unlikely to take the public sphere into account; they are too busy trying to salvage a form of "core rationality" of the scientific enterprise to reflect upon the foundation itself.³² This is part and parcel of standard scientific enquiry. Thomas Kuhn's theory, for example, has been summarised in these terms;

"A normal scientist must be uncritical of the paradigm in which he works. It is only by being so that he is able to concentrate his efforts on the detailed articulation of the paradigm and to perform the esoteric work necessary to probe nature in depth. It is the lack of disagreement over fundamentals that distinguishes mature, normal science from the relatively disorganized activity of immature pre-sciences".³³

And further,

"It is through their confidence in the adequacy of a paradigm that scientists are able to devote their energies to attempts to solve the detailed puzzles presented to them within the paradigm, rather than engage in disputes about the legitimacy of their fundamental assumptions and methods. It is necessary for normal science to be to a large extent uncritical. If all scientists were critical of all parts of the framework in which they worked all of the time then no detailed work would ever get done".³⁴

This may be all very well for standard scientific research but is inappropriate as regards medical research involving human subjects. It is a far cry from Jay Katz's collective call for a 'persistent educational effort' for medical researchers.³⁵ There is nothing wrong with his pedagogical solution *per se* but for the fact that it is applied to a model of scientific reasoning, a characteristic of which is to encourage scientists to be unreflective about the overall research paradigm. What, however, if the paradigm or "disciplinary

³²Thus, for example, the basis of Popper's theory of falsification is self-defeating. Beck, fn 16 above at 166.

³³Chalmers, fn 13 above at 92.

³⁴Chalmers, fn 13 above at 98.

³⁵"Only a thoughtful and persistent educational effort...can bring about real change in long-standing practices and thereby give some meaning to the suffering of those who were harmed by human experimentation." See Katz, *J Experimentation with Human Beings* (2nd edn, 1973) at p. 4.

matrix", as Kuhn later referred to it,³⁶ endorses withholding treatment from individuals suffering from syphilis ?

The professions are taught or indoctrinated to think along certain lines; in short, they are trained to adopt and gradually internalise a method of reasoning or 'thought collective'.³⁷ Thus, for example, doctors and other professionals are trained to think in a certain way; they are taught to rationalise according to certain conditions, traditions and precepts. The thought collective of standard scientific enquiry, along with standard scientific reasoning, has also been imported into medical research. Thus, the parameters within which medical researchers analyse are institutionally defined.

According to standard scientific enquiry upon which medical research is based, the thought collective does not encourage dialogue with the objects of research - probably because there is no need for standard scientists to enter into a dialogue with the objects of their research.

Consider the exchange between the researcher, Dr Baum, and a potential research subject, Mrs Thornton, to which we have already referred.

Mrs Thornton expressed her opposition to entering the trial in the following way;

"I felt isolated, selfish, let down, ill-prepared for considering the options for this unknown disease of DCIS which would obviously affect my life and health. The impersonality of this trial proposition seemed to be attempting to deprive me of one of the most important factors of healing, continued confidence in 'my' team, whilst accentuating negative aspects of chance rather than choice."³⁸

³⁶In the general sense of the word as referred to in the *Postscript* to the 1970 edition of *The Structure of Scientific Revolutions* where Kuhn distinguished between a general sense of the word (*disciplinary matrix*) and a narrow sense of the word (*exemplar*).

³⁷The social anthropologist Mary Douglas describes a professional collective as one which 'leads perception and trains it and produces a stock of knowledge'. This includes drawing up and maintaining criteria as regards what constitutes a reasonable question and a true or false answer. In short, it provides the context and sets the limits for any evaluative judgment about what is objective. See Douglas, M *How Institutions Think* (1987) at p. 12 et seq.

³⁸Thornton, fn 25 above at 19.

The reason for this lies in the difficulty of explanation or the efficient use of language. Baum expresses this when he writes,

“I therefore absolutely agree with Mrs Thornton that achieving ‘informed consent’ within two weeks of the diagnosis of DCIS in a woman who thought herself well until submitting a screening mammography, is an absurdity !”³⁹

He *cannot* bridge the gap between scientists and subjects in the time available in practice. He is enlightened to the extent that he applauds Mrs Thornton’s decision to speak up for herself and others in her position and he proudly acknowledges the fact that he and some other colleagues encouraged Mrs Thornton to air her views.⁴⁰ His approach fails, however, in that Mrs Thornton was *invited* to air her views. The dialogue thus provides the classic model for the subject of this thesis. Rather than rely on the permission or the arbitrary good will of Baum and his like, research subjects as well as the rest of the community should have an opportunity *as of right* to air their views in the medical research debate, including questions regarding the design of clinical trials. As Mrs Thornton says, little is known about the attitudes of patients as compared to the doctor, the lawyer and the ethicist as regards controlled clinical trials,⁴¹ the exception being, as discussed in the following chapter, is when the threat of litigation arises. The public, however, have a right to inform and be informed by the medical research debate.⁴² This necessarily involves participation, which, as MacCormick has written, lies at the core of a viable definition of democracy;

“It is not enough that all should decide; it is important that each is the equal of every other when it comes to deliberating and deciding. At least, each adult citizen (or perhaps each adult resident) of a state should have, in principle, an equal opportunity with every other to participate in political processes.”⁴³

³⁹Baum, fn 26 above at 23-24.

⁴⁰Baum, fn 26 above at 23.

⁴¹Thornton, fn 25 above at 19.

⁴²See Habermas on the role of the public sphere, fn 3 above at 359.

⁴³MacCormick, N ‘Constitutionalism and democracy’ in Bellamy R (ed) *Theories and concepts of politics: An introduction* (1993) at p. 142.

In essence, there is a role for the public sphere in the medical research process, namely, as a warning system which, despite being unspecialised, is sensitive throughout society.⁴⁴ It represents public opinion as opposed to providing decisions. Hence, it does not bear the responsibility of building a consensus; rather it is a network of communicating information and points of view which are then filtered and synthesised so that they constitute the distillate of public opinion.⁴⁵

2.4. MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

A working definition for medical research is that it is a planned study which has a well defined objective. A researcher may not divert from the agreed protocol as to do so is to undermine the project.⁴⁶ The knowledge gained as a result of research is designed to contribute to existing medical knowledge. It may or may not involve human subjects. For current purposes, the term 'research' refers exclusively to research involving human subjects, unless otherwise stated.

Experimentation differs from research to the extent that it is empirical and is subject to no pre-arranged plan.⁴⁷ Every medical intervention involves a degree of experimentation. One must depart from standard practice for methods of treatment to advance. This is what is meant by 'innovation'. Trying out new procedures over established practice does not in itself constitute a basis for negligence; the problem remains as to how far a physician may depart from standard practice and his conduct can still qualify as an acceptable innovative attempt.

⁴⁴"From the perspective of democratic theory, the public sphere must, in addition, amplify the pressure of problems, that is, not only detect and identify problems but also convincingly and influentially thematize them, furnish them with possible solutions, and dramatize them in such a way that they are taken up and dealt with by parliamentary complexes." Habermas, fn 3 above at 359.

⁴⁵Habermas, fn 3 above at 360.

⁴⁶Mason, J K and McCall Smith, R A *Law and Medical Ethics* (4th edn, 1994) at 350.

⁴⁷See Dickens, B M 'What is a medical experiment?' (1975) 113 Can Med Ass J 635.

Innovation implies a renewal of attitudes. A modern example would be laparoscopic surgery, or keyhole surgery, as it is more commonly known. This surgery constitutes an advance in existing technique and is a model of innovation. Experimentation refers to the use of a completely new process which has not been subject to appraisal but which might be acceptable as a last ditch attempt.⁴⁸ What, then, if the attitudes of the time are unable to accommodate such an idea? New ideas in medicine, as we saw in Chapter One, have met with considerable resistance.⁴⁹ One wonders sometimes whether it is not a miracle that progress in medicine has been achieved at all, given the intellectual straightjackets within which it has been confined.

This question arose in one of the first English cases on human experimentation which still provides the legal standard for experimentation⁵⁰ - a position which is, as the following section will show, erroneous.

In *Slater v. Baker and Stapleton*,⁵¹ an English surgeon treated the plaintiff's broken leg by breaking it and disuniting the callous from the leg after it had been set by another surgeon. In so doing, Dr Baker decided to try a device which he had recently developed and which he believed would extend the leg. The plaintiff's leg failed to heal and he sued for breach of contract. In upholding the plaintiff's claim, the court held that,

"For anything that appears to the Court, this was the first experiment made possible with this new instrument; and if it was, it was a rash action, and he who acts rashly acts ignorantly: and although the defendants in general may be as skilful in their respective professions as any two gentlemen in England, yet the Court cannot help saying, that in this particular case they acted ignorantly and unskilfully, contrary to the known rule and usage of surgeons."⁵²

⁴⁸The Declaration of Helsinki which approves of "...saving life, re-establishing health or alleviating suffering." See (1992) 339 Lancet 15.

⁴⁹Indeed such an attitude was inherent in the ethics of early Egyptian medicine. See Mason and McCall Smith, fn 46 above at p. 4. See also Chapter One, Section 1.1.1.3.

⁵⁰Nelson-Jones, R and Burton, F *Medical Negligence Case Law* (2nd edn, 1995) at p. 65.

⁵¹(1797) 95 ER 860.

⁵²(1797) 95 ER at 863.

The court's reasoning, however, is flawed; it is based on paralogic and it is invalid. The conclusion does not follow to the extent that it relies on the consequences. The court's reasoning can be summarised thus;

- (i) If you do something rashly, you may get a bad result.
- (ii) If you do something for the first time, you may get a bad result.
- (iii) Therefore if you do something for the first time, you are acting rashly.

The error lies in the assumption that because the consequences are the same, the antecedents are the same. However, you could do something for the first time and still get a bad result even though you had considered it very fully and were in no sense 'rash'.

A further question arises; was Dr Baker's method a minor deviation from customary practice or was it a 180 ° turn ? The accepted method at the time, as a host of surgeons testified at the trial, involved applying compression until the broken bone knitted together.⁵³ However, Dr Baker's method was the first recorded instance of the use of modern treatment. It is common accepted practice in modern medicine to treat a broken leg by putting it in traction, *not* compression.

In essence, Dr Slater was unfairly done by. The standard set out in the judgment, "ignorantly, and unskilfully, contrary to the known rule and usage of surgeons" is not only false but one is also reminded of Lydgate's adversaries in *Middlemarch* who were wary of anything remotely "new fangled", including, the need to conduct research.⁵⁴ This too, is reflected in the judgment. Dr Baker, is referred to earlier on in the judgment in the most reverential of terms;

⁵³(1797) 95 ER at 861.

⁵⁴See Eliot, G *Middlemarch* Harvey, W J (ed) (1985) at p. 119. It must be remembered that the main reason why Lydgate moved to Middlemarch was to conduct research; "He went to study in Paris with the determination that when he came home again he would settle in some provincial town as a general practitioner, and resist the irrational severage between medical and surgical knowledge in the interest of his own scientific pursuits, as well as the general advance". See p. 174.

“...Baker has been above 20 years the first surgeon in St Bartholomew’s Hospital, reads lectures in surgery and anatomy, and is celebrated for his knowledge in his profession as well as his humanity; and to charge such a man with ignorance and unskilfulness upon the records of this Court is most dreadful.”⁵⁵

However, the attitudes of the time come through a few lines down;

“When we consider the good character of Baker, we cannot well conceive why he acted in the manner he did but many men very skilful in their profession have frequently acted out of the common way for the sake of trying experimentation”.⁵⁶

It is arguable that *Slater v. Baker and Stapleton* was a cornerstone for medical malpractice claims;⁵⁷ the principles laid down in it should, however, never have been applied to experimentation. Innovation demands an outlook which is inherently prospective, something which the judges and the surgeons in the case regarded with both distaste and caution.

2.4.1. THE OBJECTIFICATION OF THE RESEARCH SUBJECT

Generally speaking, medical progress could not be achieved without the participation of both human and animal research subjects.⁵⁸ Conflict arises when the subjects become objects of organised research. For a doctor engaging in medical research, the distinction between an animate and an inanimate object may become blurred particularly through the influence of the rest of the scientific community, whose research is object based.

⁵⁵(1797) 95 ER at 862.

⁵⁶(1797) 95 ER at 862.

⁵⁷Terry, N ‘The Malpractice Crisis in the United States: A Dispatch from the Trenches’ (1986) 2 PN 145 in Kennedy, I and Grubb, A *Medical Law: Text & Materials* (1994) at 90.

⁵⁸This work is dedicated to the study of research involving human subjects only; however, it is submitted that both categories of research subjects are worthy of legal protection. Many of the works of Peter Singer are devoted to the expression of animal rights.

Objective statements and criteria are the staples of scientific rationality. They form an integral part of what has been referred to above as the ‘thought collective’ of the scientific profession.⁵⁹ Scientists are trained to report their findings in a particular manner; specialised terminology and structure are tools of the trade. They conduct experiments according to criteria which guide what constitutes a reasonable question and a true or false answer.⁶⁰ As Gee and Mason point out, “The scientist is accustomed to the rules of scientific enquiry, to making observations, forming hypotheses from them, conducting experiments to check the hypotheses and, thus, formulating theories. The object is to establish truth - there are no compromises.”⁶¹ No compromises entails that the thought collective of scientists provides the context and sets the limits for any evaluative judgment about what is objective.⁶² No compromises, however, has sinister undertones if we remind ourselves of the experiments conducted during the Third Reich.

The reports which Dr Rascher sent Himmler, for example,⁶³ are structured in a way which would be acceptable to modern medical writing. The letters are written in a passive tense and symptoms are recognised and listed in the order in which individual body parts are affected.⁶⁴ Indeed, reading through the documentation set out in Alexander Mitscherlich’s book, *Das Diktat der Menschenverachtung*⁶⁵ it is easy to forget that the research subjects (*Versuchspersonen*) referred to in the letters as ‘VP’s, are in fact human beings.⁶⁶ The abbreviation militates against being aware of the

⁵⁹See generally Fleck, L *The Genesis and Development of a Scientific Fact* (1935, (tr) 1979).

⁶⁰Douglas, fn 37 above at 13.

⁶¹Gee and Mason, fn 12 above at 87.

⁶²*Ibid.*

⁶³See Chapter One at Section 1.4.4.

⁶⁴For example see Doc. No. 428 in Mitscherlich, fn 5 above at 40.

⁶⁵Mitscherlich, fn 5 above.

⁶⁶“Die VPn werden mit voller Fliegeruniform, Winter - und Sommer - Kombination und Fliegerhaube bekleidet ins Wasser gebracht.” Which translates as, “The VPs are placed in the water wearing a full winter and summer pilot’s uniform and a pilot’s cap”. Mitscherlich, fn 5 above at 37.

humanity of the objects of research.⁶⁷ The research subjects had to be aryan or “*rein nordisch*” for Rascher to recognise their humanity.⁶⁸

In the case of the *Tuskegee* experiment, the subjects’ humanity was also overridden on the grounds of race. Indeed, the experiment was viewed by some as an act of genocide on a par with Nazi Germany. An editorial which appeared in the *Los Angeles Times* qualified the accusation that Public Health Service (PHS) officials had persuaded black men to become human guinea pigs by adding: “Well, perhaps not quite that [human guinea pigs] because the doctors obviously did not regard their subjects as completely human”.⁶⁹

In the *Hyman*⁷⁰ case, where patients were injected with cancer cells as part of a study of the immune system’s response to cancer,⁷¹ the humanity of the patients was qualified with reference to the fact that they were terminally ill. The patients represented an ideal opportunity for Dr Southam to test a hypothesis concerning cancer,⁷² the rationale being that they were going to die anyway. Dr Mandel, who actually carried out the research opted, for a slightly different interpretation of the rationale, justifying the research given the “insufficient medical attention to the long term, chronically ill patients.”⁷³ His Hippocratic aspirations, however, did not extend to telling the patients that they were being used as research subjects.

⁶⁷“Sobald die Unterkühlung bei diesem Versuchen minus 28° erreicht hatte, starb die VP mit Sicherheit trotz aller Versuche zur Rettung.”, or, “As soon as the temperature sunk to minus 28°, the VP died despite all rescue attempts.” See a letter from Dr Rascher to Himmler, dated September 10, 1942 Doc. No. 1618 - PS in Mitscherlich, fn 5 above at 38-39.

⁶⁸See Doc. No. 323 in Mitscherlich, fn 8 above at 44.

⁶⁹See Jones, J H *Bad Blood: The Tuskegee Syphilis Experiment* (2nd edn, 1993) at p. 12.

⁷⁰ 15 N. Y. 2d 317, 206 N. E. 2d 338; N. Y. 2d 397 (1965).

⁷¹The case is discussed in detail in Chapter One above at section 1.5.1.

⁷²That the rejection of cancerous cells transplanted to a person suffering from cancer was delayed as compared to a healthy person.

⁷³Langer, E ‘Human Experimentation: New York Verdict Affirms Patient’s Rights’ in Gorovitz S, Macklin R, Jameton, A L, O’Connor, J M, Sherwin. S (eds) *Moral Problems in Medicine* (2nd edn, 1983) at 628.

Objective experimentation, as formally introduced by Claude Bernard,⁷⁴ was never qualified in relation to the context of medical research involving *human beings*. As a consequence, the reasoning behind standard scientific enquiry was extended without adequate consideration of the changed circumstances.

Objective statements used in medical research are impersonal by definition. Language which is impersonal reduces individuals to objects as opposed to rational human beings capable of making choices. The choices available to an individual engaged in research are translated into what Alderson refers to as matters of function and manipulation instead of identity and relationship.⁷⁵ We must not lose sight of the identity of research subjects; it is an essential element of the research process;

“Whatever the rights and wrongs of any experimentation on any patient in the one case, at least that residue of identification is left him that it is his own affliction by which he can contribute to the conquest of that affliction, his own kind of suffering which he helps to alleviate in others; and so in a sense it is his own cause. It is totally indefensible to rob the unfortunate of this intimacy with the purpose and make his misfortune a convenience for the furtherance of alien concerns.”⁷⁶

Moreover, we cannot afford to overlook the relationship between objective terminology used in medical research and its effect on research subjects.

2.4.2. THERAPEUTIC RESEARCH

In an effort to distinguish the various categories of medical research, it has become customary to divide research into therapeutic and non-therapeutic categories. The distinction is implicit in the Declaration of Helsinki (1964), the introduction of which states that,

⁷⁴Bernard, C *An Introduction to the Study of Experimental Medicine* (Copley Green, H(tr) 1957).

⁷⁵Alderson, P ‘Did Children Change, or the guidelines?’ (1992) 80 Bull Med Eth 22.

⁷⁶Hans Jonas in Beauchamp, T L and Walters, L *Contemporary Issues in Bioethics* (1982) at 532. It must be added, however that Personalisation, however, ignores the concept of anonymised research as in the case of randomised clinical trials (RCTs), for instance; a consequence of research by numbers is that it does not have to be personalised.

“In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research the essential object of which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research.”⁷⁷

Therapeutic research is, thus, defined as that which is “essentially diagnostic or therapeutic for a patient”; this is reinforced by paragraph II 6 which provides that a physician can combine research with professional care to the extent that the research includes “potential diagnostic or therapeutic value for the patient”. Any other research is purely scientific and is commonly referred to as non-therapeutic.

Objective terminology can be subliminally persuasive - or, as George Orwell put it, certain words add an “air of scientific impartiality to biased judgements”.⁷⁸ By definition, the category of therapeutic research incorporates a notion of treatment,⁷⁹ which is somewhat weighted with the hope of recovery;

“‘Therapeutic’ is an oddly fuzzy, unscientific word; it expresses possibly unfounded hopes for the future as if they were present realities, it confuses the aim of research with the activity. The word offers a licence for researchers to claim good intentions. Yet scientific rigour would assess research in terms of outcome, effectiveness and efficiency.”⁸⁰

Thus, the term ‘therapeutic’ implies that the research will benefit the individual, an outcome which is by no means clear, in view of the very nature of research. It may benefit or harm the individual or it may have no effect whatsoever. The outcome is not known yet the category of therapeutic research lays claims to certainty which may only be established once the research is completed. Hence,

“A new drug being tested could not strictly be described as therapeutic until its benefits and risks are known. For these reasons, all research is in a sense ‘non-therapeutic’.”⁸¹

⁷⁷The Declaration of Helsinki (1964) as reprinted in Appendix B in its revised form.

⁷⁸Words such as *phenomenon*, *element*, *objective*, *categorical*, *effective*, *virtual*, *basic*, *exhibit*, See Orwell, fn 9 above at 352.

⁷⁹Kennedy and Grubb, fn 58 above at 1031.

⁸⁰Alderson, fn 75 above at 23.

⁸¹*Ibid.*

In short, whilst the terminology used in medical research appears to be objective, neutral and unbiased, the way in which it is defined and exercised involves the use of value judgments. Instead of abolishing the term 'therapeutic research' to clarify such uncertainty, as some have suggested,⁸² the role of rhetoric in the medical research process must be understood.

2.4.3. RHETORIC AND THE POLITICAL USE OF LANGUAGE

Language can be used to express ideas as well as to conceal or prevent thought.⁸³ It can be used to present a case selectively. Persuasion plays a central role in the medical research process. A researcher must persuade a person to become his research subject. He or she must persuade a funding body to finance the project, must persuade a research ethics committee to approve the proposal and must persuade a journal to publish the findings. Persuasion is reinforced by the use of metaphors which influence the way in which we see regard illness. The prevailing metaphor for illness is based in the language of war;

"Punitive notions of disease have a long history, and such notions are particularly active with cancer. There is the 'fight' or 'crusade' against cancer; cancer is the 'killer' disease; people who have cancer are 'cancer victims'...[T]he understanding of cancer supports quite different avowedly brutal notions of treatment...there can be no question of pampering the patient. With the patient's body considered to be under attack ('invasion'), the only treatment is counter-attack."⁸⁴

Disease is seen as being provoked by alien organisms to which the body must respond by invoking its own military forces.⁸⁵

Rhetoric helps to justify medical research. Thus,

⁸²See Kennedy and Grubb, fn 57 above at 24 who suggest that part of a physician's duty would be to make it clear to the patients that the prime beneficiary of the research is the researcher and not the patient.

⁸³Orwell, fn 9 above at 359.

⁸⁴See Sontag, *S Illness as Metaphor and Aids and its Metaphors* (1991) *inter alia* at 59-65.

⁸⁵Sontag, fn 84 above at 95.

“One can reduce the strategy to a formula: first detach your agenda from its partisan origins, from its history, and then present it as a universal imperative, as a call to moral arms so perspicuous that only the irrational or the godless (two categories often conflated) could refuse it. You can do this in many ways, but one way, tried and true, is to appropriate vocabulary that is already an honoured one and then “spin” it so that it will generate the conclusions - the marching orders - that are the content of your politics.”⁸⁶

A good illustration of rhetoric in the medical research debate is to be found in Carolyn Faulder’s book, *Whose Body is it ?*⁸⁷ Her analysis is concerning the use of RCTs in medical research is both well researched and well argued, her main thesis being that people must know whether they are being entered into clinical research trials. She begins by stating that “...too often we allow our priorities in health care to be determined by emotional appeal rather than by a cooler appraisal of the total needs of the population”.⁸⁸ Admirable sentiments which are, however, undone by the opening lines of her book; “In August 1981, an eighty-three year old widow, Mrs Margaret Wigley, following an operation for bowel cancer...”.⁸⁹ Or “Doctors are invariably middle class...”.⁹⁰ Her treatise is both polemical and rhetorical and illustrates how information can be presented or manipulated to toe a particular party line. This is a universal charge which can be levied at other participants in the medical research debate. Be that as it may, a consequence is that there is a danger that selective presentation can contribute to framing an ideology which can be used to rationalise almost any end. This is particularly appropriate as regards the use of scientific terminology which can be used to fit a requisite agenda whilst appearing to be neutral. Language can be tailored to meet a particular end. This is an issue which has been addressed in relation to language, medicine and the law.

⁸⁶Fish, S *There’s no such thing as free speech and it’s a good thing too*. (1994) at 8.

⁸⁷(1985).

⁸⁸See fn 87 above at 31.

⁸⁹See fn 87 above at 9.

⁹⁰See fn 87 above at 35.

The relationship between language and the law is one which is characterised by the art of persuasion. Gee and Mason suggest that this is because the language of law blurs the distinction between logic and rhetoric, the former concerning the formulation of argument and the latter the art of persuasion.⁹¹ How else is the strategy which lawyers employ when examining and cross examining witnesses to be viewed ? The sequence of questions is a product of legal training.⁹² It also, however, forms part of medical training as, for instance, in the making of a diagnosis.

Gee and Mason, however, write about the 'chain of reasoning' in relation to lawyers involved in litigation only. They compare the legal and the medical profession by drawing a distinction between deduction and induction. Lawyers are concerned with the former, that is to say, the rules of good argument whilst scientists are concerned with the latter;

"The scientist is accustomed to the rules of scientific inquiry, to making observations, forming hypotheses from them, conducting experiments to check the hypotheses and, thus, formulating theories. The object is to establish the truth - there are no compromises. The court, on the other hand, is there to resolve a dispute between two parties, either between two persons in a civil action or between an individual and the state in a criminal action. There may be an absolute answer to the dispute, with clear facts supporting one side only but more often, the issues are clouded - there are views in favour of both sides and facts which can be adduced in support of either point of view. The court procedure then takes the form of debate, in which the opposing points of view are espoused by the lawyers for each side who try to present their client's case in the most favourable light."⁹³

An implication is that lawyers deal in the deductive currency of validity whereas scientists deal in the inductive currency of truth. The type of thinking which scientists use in reaching conclusions results in "an opinion...which, while not being absolutely certain, is the best possible explanation for the known facts."⁹⁴ In short, lawyers are concerned with versions of the truth whereas scientists deal with truth.

⁹¹Gee and Mason, fn 12 above at 88.

⁹²Ibid.

⁹³Gee and Mason, fn 12 above at 87.

⁹⁴Gee and Mason, fn 12 at 89.

It is arguable that the party with the greater understanding, and who is best able to make its description stick,⁹⁵ is able to influence the medical research debate disproportionately. Thus, the party whose selective presentation is the most convincing wins. Understanding the rhetoric of research involves a consideration of the individuals in the process and being aware of issues such as the benefit to society, careers of researchers, investments by pharmaceutical companies and so on. In short, terminology must be used in such a way as to clarify and not to obfuscate the socio-political dynamics of the process.

The reflective use of language ascribes dignity to the individual by involving him as a research *subject* as opposed to an anonymous, disenfranchised research *object*. Research subjects are thereby accorded their full status as human beings capable of making autonomous choices. This further avoids casting them as victims, a role which opens the door to a paternalistic offer of protection for their 'best interests'. Research subjects must be protected but not at such a price. As will be examined later on, the best interests test lames and erodes the identity of research subjects. Pressed to its extreme, it does no more than move the research subject from the frying pan of uncertainty into the fire of overprotection.⁹⁶

2.4.3. NON-THERAPEUTIC RESEARCH

The intention in carrying out non-therapeutic research is to acquire scientific knowledge.⁹⁷ The term non-therapeutic research refers to research which will not immediately benefit the subjects involved; these can be subdivided into healthy volunteers and captive patients subjects. Is this form of research to be regarded as 'purely scientific'? Is it possible to dissociate the subjective from the objective result? Is there such a thing as the "additional attention" effect? The unexpected or untoward

⁹⁵Through money, connections though arguable in the present context, through the position of power which the medical community occupy

⁹⁶See Chapter Three.

⁹⁷Mason and McCall Smith, fn 46 above at 351.

effect which some research subjects experience on receiving medical attention must not be underestimated. This is particularly relevant as regards patient volunteers, who despite having been told that the medical attention they receive will be of no benefit to them, may instinctively believe that it will be so.

By definition, non-therapeutic research incorporates the notion of helping a future generation, an idea with which we are not entirely at ease. Traditional ethical principles, such as those within Kantian moral theory, stress the autonomy of moral reason and the responsibility towards those in our immediate proximity but not necessarily towards future generations.⁹⁸ A definition of proximity is needed for the medical research process which acknowledges both the long and short term. The tension between short and long termism is particularly noticeable if we question the effectiveness of the distinction between therapeutic and non-therapeutic research.

2.4.4. IS THE DISTINCTION EFFECTIVE ?

The distinction between therapeutic research and non-therapeutic research is not as neatly polarised as some of the literature might suggest. For example, treatment in the context of a research project may amount to testing various new procedures in order to determine which is superior. There may be occasions when a physician continues with tests, even after he has gained the information required to answer his research hypothesis.⁹⁹ This curiosity is driven by the enthusiasm of the researcher but on the face of things is of no additional advantage to the subjects. It could, however, be suggested that such testing is legitimate. How else is a physician / researcher to test the relapse rate of the condition ? There may still be genuine doubt as to the best method of treatment. The researching physician would, arguably, still be acting in the totality of the patient's best interests as opposed to his immediate needs. He would also be

⁹⁸“The ethical universe is composed of contemporaries, and its horizon to the future is confined by the foreseeable span of their lives.” Jonas, H ‘Technology and Responsibility: Reflections on the New Task of Ethics’ in Jonas, H *Philosophical Essays: From Ancient Creed to Technological Man* (1974) at 7.

⁹⁹Fried, C ‘Informed Consent and Medical Experimentation’ in Beauchamp and Walters, fn 76 above at 541.

considering the needs of future generations. Our current views of research, however, do not take this into account explicitly, but, instead, encourage analysis which is rooted in the short term. To what extent is this approach encouraged by those who have vested interests to protect ? One is reminded of Galbraith's "culture of contentment" insofar as a short term approach is a tactic of the contented majority to retain their position of authority. This takes us back to the discussion above concerning pharmaceutical companies and vested interests.¹⁰⁰

The impact of the categories of therapeutic and non-therapeutic on the law has been discussed traditionally in terms of negligence which is, in itself, a restrictive short term approach. It is argued that the standards of disclosure required differ according to which category of research is being conducted.¹⁰¹ Under both English and Scottish law, for example, the treatment of a patient without his or her consent requires specific justification.¹⁰² Yet there is still evidence that patients are recruited who are unaware that their treatment forms part of a research project.¹⁰³ An action in battery or negligence might arise were a patient not told that this is the case; an explanation of the broad nature of the procedure intended requires that a patient be told that it forms part of a trial.¹⁰⁴ The shortcomings of this approach, however, are that it is anchored in an interpretation of the duty of care as restricted to the individual harmed, in itself, a cornerstone of the English law of tort and the Scottish law of delict.

Consider, for example, the "neighbour" principle as articulated by Lord Atkin in *Donoghue v. Stevenson*;

"The rule that you are to love your neighbour becomes in law, you must not injure your neighbour; and the lawyer's question, Who is my neighbour ? receives a restricted reply. You must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour. Who, then, in law is my neighbour ? The answer seems to be - persons who are so closely and

¹⁰⁰See Galbraith, fn 19 above at 20.

¹⁰¹See Brazier, fn 11 at 416 et seq. This issue is discussed in further detail in Chapter Three.

¹⁰²See *Sidaway v. Board of Governors of the Bethlem Royal and the Maudsley Hospital* [1985] 1 All ER 643 and also *Hunter v. Hanley* 1955 SC 200.

¹⁰³Brahams, D 'Clinical Trials and the Consent of the Patient' (1982) 226 Practitioner 1829.

¹⁰⁴Kennedy and Grubb, fn 57 above at 1045.

directly affected by my act that I ought reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called in question".¹⁰⁵

Lord Atkins's dictum is not the *ratio decidendi* of the case and was never intended to be an exact comprehensive statement of the law.¹⁰⁶ Be that as it may, Lord Atkin was not speaking about the law as a whole but about negligence; in other words, he was asking to whom do I owe a duty of care? A restrictive response such as the one given by Lord Atkin then becomes inappropriate as regards medical research. My neighbour in medical research includes future generations which necessitates an extension of the neighbour principle. How can we make these decisions, given the complexity of the knowledge required? Generally speaking, the knowledge is not available to the individual but is a matter of science.¹⁰⁷ Foreseeability requires mental expertise. Nowhere is expertise more vital than in relation to the assimilation of risks - and this forms an integral part of the medical research debate.

2.5. RISKS: THE JUSTIFICATION FOR RESEARCH

2.5.1. THE RISK / BENEFIT ANALYSIS

2.5.1.1. GENERAL PRINCIPLES

The risk / benefit analysis refers to the balancing exercise which weighs the extent to which risks may be justified in order to achieve the overall benefit. It provides that research or experiments are justifiable only when related to the anticipated scientific or clinical benefit. The risk / benefit analysis is enshrined at both an international and national level.

¹⁰⁵[1932] AC 562, HL at 580.

¹⁰⁶Brazier, M *The Law of Torts* (2 edn, 1992) at 173.

¹⁰⁷Delanty, fn 3 above at 11.

2.5.1.2. INTERNATIONAL LEVEL

Paragraph I. 4 of the Revised Declaration of Helsinki (1975)¹⁰⁸ insists that,

“Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.”

Paragraph I. 5 further provides that,

“Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interest of science and society.”

2.5.1.1.3. National Level

2.5.1.1.3.(I) The United Kingdom

At a national level, the Royal College of Physicians Guidelines¹⁰⁹ provide a basis for the risk / benefit analysis. In particular, paragraph 5.8 of the Royal College of Physicians guidelines establishes the duty of a research ethics committee to conduct such an analysis when considering a research protocol:

“A key decision in the assessment of proposed research is whether the risk or inconvenience caused to the patient is justifiable in relation to the value of the information sought. This process is sometimes referred to as risk / benefit analysis. We believe that it assists Committees to arrive at good decisions if they are provided with as precise an estimate as possible of both risk and the benefits inherent in research.”¹¹⁰

¹⁰⁸Reproduced in Appendix B.

¹⁰⁹The Royal College of Physicians of London *Research Involving Patients* (1990) paras 5.8-5.26.

¹¹⁰*Ibid.*

2.5.1.1.3.(ii). Germany

Section 1(1) § 40 of the German Drugs Code (AMG) provides that a trial involving non-therapeutic research may go ahead only if the risks involved can be justified by the possible benefit which the new medication has to offer.¹¹¹ Therapeutic research involves a different assessment of risks. § 41 (1) alters the risk / benefit parameter to encompass the condition of the likelihood, according to current medical knowledge, that the trial will save the patient's life, cure the patient or relieve the symptoms of his illness.¹¹² A clinical trial may only go ahead if the risks involved are justifiable in accordance with their possible benefit.¹¹³

2.5.1.1.3.(iii). The United States

The Food and Drug Administration guidelines include the risk / benefit analysis as part of the criteria for IRB approval of research. The guidelines expressly provide that the risks to the research subjects must be minimised by using procedures which are consistent with "sound research design".¹¹⁴

As regards the definition of 'risk', the guidelines state that,

"Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits or therapies subjects would receive even if not participating in the research)."¹¹⁵

There are, however, different gradations of risk; it is not a static property.

¹¹¹ See Appendix D.

¹¹² See Appendix D.

¹¹³ See the Kohlhammer *AMG Kommentar* (1994) at p. 13 and also § 38 (40) (1) Nr 1 AMG.

¹¹⁴ § 46.111 (a) (1) (i) 45 Code of Federal Regulations Part 46: Protection of Human Subjects (Revised as of October 1, 1989 as reproduced (selectively) in van den Dael, W and Müller-Salomon, H *Die Kontrolle der Forschung am Menschen durch Ethik-Kommissionen* (1990) at 141.

¹¹⁵ § 46.111 (2) in van den Dael and Müller-Salomon, fn 114 above at 142.

2.5.1.4.1. Risk

The Royal College of Physicians guidelines for therapeutic research, for example, distinguish between research involving ‘less than minimal risk’ (e.g. giving a urine sample)¹¹⁶ and that involving ‘minimal risk’ (e.g. chance of a mild reaction such as a headache but also includes the remote chance of serious injury or death).¹¹⁷ It is recommended that a minimal risk should only be undertaken if the risk is comparatively small in relation to the risks which the patient has incurred during the course of his illness, if the disease is serious, where the knowledge gained from the research is likely to be of great practical benefit, where there are no other means of obtaining the same knowledge and where the patient gives fully informed consent. However, in the case of non-therapeutic research, it could be argued that a patient should not be subjected to a minimal risk just because one in two hundred might benefit.

Let us say that a scientist came up with a hypothesis as to the cause of Alzheimers which necessitated performing a brain biopsy. This of course would be non-therapeutic research as the motivation on behalf of the scientist is purely scientific and demonstrates the distinction between benefit to the present and to future patients. Could the risk to the patient be justified in view of the fact that no benefit will accrue to him ? Suppose the answer depended upon the results of a lumbar puncture ? This process might well involve considerable discomfort and is certainly not without risk but does not carry the same hazards as an invasion of the brain. Yet again, suppose the scientist could test his hypothesis by taking a blood sample ? An intervention of this minimally invasive nature could easily be justified. However, what about the grey area in-between the first example and the third ? Are the risks which attach themselves to performing a lumbar puncture reconcilable with what still only amounts to a hypothesis towards trying to find a cause rather than the cure of a disease ? Clearly the risks have changed and with this, the justification has changed irrespective of the scientific value of the research. Where should the line be drawn ? Furthermore, by whom should it be drawn ?

¹¹⁶See para 5.10 of Royal College of Physicians, fn 109 above at 9.

¹¹⁷See para 5. 11 of Royal College of Physicians, fn 109 above at 9.

The Declaration of Helsinki provides that as regards non-therapeutic research,

“The investigator or the investigating team should discontinue the research if in his / her judgment it may, if continued, be harmful to the individual”.¹¹⁸

and further at paragraph III.4 that

“...the interest of science and society should never take precedence over considerations related to the wellbeing of the subject”.

If the guidelines were followed literally, research involving the possibility of serious risks would rule out the use of volunteers.¹¹⁹ A question would then arise as to whether such research were ever justified other than by using the researchers themselves as subjects.¹²⁰ As a consequence, research which might benefit humanity might be stultified or worse, it might drive such research underground thus putting the subjects in double jeopardy.

The medical researcher is responsible for the weighing up of risks which must be done both before and during the clinical trial. In attempting to test the foreseeability of the possible risks and benefit, he must consider the results of the tests carried out on animals before the start of the trial. If the risk / benefit analysis suggests significant danger, the decision as to whether it is justifiable is one for the researcher to make. The only opportunity for his assessment to be appraised lies in its submission for evaluation by a research ethics committee. The decisions of the committee, however, are reached on the basis of consensus of a select class of individuals. The nature of this consensus regarding the principles for medical research affects the justification for its practice. It is vital that the justification invoked is the product of pluralistic deliberation. In essence, we need to know what the general public think. We need to know, for example, whether they think that it is justifiable to allow patients with Alzheimer's disease to take

¹¹⁸Para III. 3.

¹¹⁹See Mason and McCall Smith, fn 46 above at 352.

¹²⁰Though, even then, would the head of department be justified in allowing it to go forward ? Almost certainly not if the risk were a serious one.

part in non-therapeutic research on behalf of others. The common good is a matter for the common man, albeit not exclusively so. The common good, however, is hard to define.

2.5.1.5.2. Benefit

Historically, the concept of utilitarianism has faltered on the uncertain conception of what is meant by the common good despite standard definitions such as the 'greatest happiness of the greatest number'. It has been argued that this definition is not only conceptually vague but also practically insignificant in view of the uncertainty in measuring it.¹²¹ This is despite the fact that contemporary utilitarians have remodelled the concept by asserting the common good is to maximise overall happiness by realising the satisfaction of choices made by autonomous individuals. This attempts to take into account the individual's interests, their desire for autonomy and their different perceptions of what it is to flourish.¹²² However, the risk / benefit calculus in medical research sometimes operates in such a way as to override the interests of the individual, especially as regards non-therapeutic research;

"Thus if overall maximisation of welfare is the supreme moral objective the individual seems to be in permanent jeopardy before the overriding interests of society. The ordinary intuitive deontological moral principles that govern our relationships, such as respect for the integrity of each other's persons, for each other's autonomy, for promise keeping, honesty, and openness, for fairness and justice are disposable whenever overall maximisation of welfare requires us to ignore them."¹²³

In its modern form and in the context of medical research, the common good refers to the greater good of humanity. Measuring risks informs us as to whether a research protocol is justifiable or not - thus, statements of risk are unavoidably evaluative. As Beck points out,

¹²¹Gillon, R *Philosophical Medical Ethics* (4th, edn 1991) at 23-24 and also Singer, P *Practical Ethics* (1979) at p. 79.

¹²²Singer at p. 80 and Gillon at p. 25, fn 121 above.

¹²³Gillon, fn 121 above at 25.

“The prevailing theoretical self-concept of science implies that the sciences cannot make value judgments with the authority of their rationality. They deliver so-called ‘neutral’ figures, information, or explanations which are to serve as the ‘unbiased’ basis for decisions on the broadest variety of interests. Which interests they select, however, on whom or what sort of potential solutions they bring into view - these are anything but neutral decisions. In other words: the sciences have developed their steering abilities independently of and beyond explicit value statements. Their possibilities of exerting practical influence lie in how they design scientific results. Thus the ‘purely objective’ interpretation of ‘need’ and ‘risk’ in the various field of action provides a cloak behind which the directions of future developments are negotiated.”¹²⁴

More importantly, however, is the fact that the shortcomings of the utilitarian model is that it presupposes a consensus as to what is both “common” and what is “good”.

We need scientists to facilitate the medical research debate by informing us of the likelihood of harm and so on. We do not, however, require them to decide what is to be done as a result. The medical research debate should also be structured in such a way as to enable a wider audience to inform research workers of what is and what is not acceptable. A consensus of what is the common good must be derived from a consensus of all those affected - that is, the community.

2.5.1.5.3. Risks: Calculability v. Estimability

In one sense, risks can be understood only by those with the necessary mathematical and physiological expertise. Not everyone, for example, will understand what is meant by a 5 % risk of incontinence following the administration of an epidural injection during the course of a clinical trial. Thus, the expression of risk depends on a certain level of understanding in the audience. The danger is that this enables those with the requisite knowledge and training to monopolise the debate; Beck refers to this as ‘primary scientization’ which leads to dominance by experts.¹²⁵ Future perspectives and possibilities are discussed within the scientific community; external or public influence is absent.¹²⁶ The monopoly of scientific rationality as regards risks can be qualified by, for

¹²⁴Beck, fn 16 above at 174.

¹²⁵Beck, fn 16 above at 158.

¹²⁶Beck, fn 16 above at 171.

example, altering the basis of definition of risks from that of calculability to that of what has been translated as estimability (*Abschätzbarkeit*). An alternative and equally plausible translation of *Abschätzbarkeit* would be foreseeability. In other words, we are looking at the difference between what we might reasonably expect to happen and what we fear might happen. The distinction is a real one. Scientists provide a key to understanding the probable risks which a research proposal entails. Thus, they play a crucial role in informing the consensus so that the principles ascertained for medical research are the product of informed reasoning. However, to consider foreseeability is to move from scientific calculation and to enter the realm of possibility. This, in turn, opens the assessment of risks to those without training, thus enabling the public to participate in the process of deciding what is justifiable and what is not.

This means that those involved in widely differing spheres of influence - for example, in politics, business and the professions - can contribute to the medical research debate.¹²⁷ Thus, the debate moves to being based on a collaborative model of well-informed dialogue as opposed to an adversarial contest between the experts and their subjects; this demands a substantial change of attitude. The result is that the public as a whole has to grow out of its sense of insecurity towards expertise and to accept it on the basis of relative equality. This includes the attitudes of the legal profession.

For example, in the case of *R v. Adams*,¹²⁸ which involved an accusation of rape, it was held that evidence of a statistical method of analysis in a criminal trial plunged the jury into inappropriate and unnecessary realms of theory and complexity deflecting them in their proper task. The prosecution case rested entirely on expert evidence in relation to the DNA profile obtained from semen on a high vaginal swab taken from the complainant. At trial, the defence were not permitted to apply the *Bayes Theorem* of probability to the statistical evaluation of the DNA profile.¹²⁹ The rationale was that the evidence trespassed on an area peculiarly and exclusively within the jury's province,

¹²⁷Beck, fn 16 above at 172.

¹²⁸[1996] 2 Cr App R 467.

¹²⁹For an explanation of the *Bayes Theorem* see Kaye, D H 'What is Bayesianism: A Guide for the Perplexed' (1988) 28 *Jurimetrics: Journal of Law, Science and Technology* 161.

namely, the way in which they evaluated the relationship between one piece of evidence and another. Although the theorem was an appropriate tool for statisticians, it was inappropriate for use in jury trials or as a means to assist the jury in their task.¹³⁰

“More fundamentally, the attempt to determine guilt or innocence on the basis of a mathematical formula, applied to each separate piece of evidence was simply inappropriate to the jury’s task. Jurors evaluated evidence and reached conclusions not by means of a formula, mathematical or otherwise, but by the joint application of their individual common sense and knowledge of the world to the evidence before them.”¹³¹

The argument is rooted in a certain view of the division of labour, one in which it is the role of judges to assist the jury. In effect, Lord Justice Rose was putting experts in their place. Note that he first states that the *Bayes Theorem* might be an “appropriate and useful tool for statisticians, but inappropriate for jury trials and *then* deflects from this contentious statement by making his main point by starting off with, “more fundamentally..” and so on. According to Rose LJ, the courts were perfectly capable of judging the evidence given in the individual case without being forced to accept the views of “scientific” experts; this type of backlash is not an uncommon occurrence in the law.

Consider, for example, the Australian medical negligence case, *F v. R*¹³² where King CJ stated that whereas much assistance could be derived from statistical evidence as to whether a doctor acted reasonably in the exercise of his professional skill and judgment, such evidence would not be decisive in all circumstances. He relied on the judgment of the Supreme Court of Canada in *Reibl v. Hughes*:

“To allow expert evidence to determine what risks are material and, hence, should be disclosed and, correlatively, what risks are not material is to hand over to the medical profession the entire question of the scope of the duty of disclosure, including the question whether there has been a breach of that duty. Expert

¹³⁰The theorem’s methodology required that items of evidence be assessed separately according to their bearing on the guilt of the accused, before being combined in the overall formula. In their Lordships view, this approach was too rigid in relation to evidence of the nature which a jury characteristically had to assess.

¹³¹[1996] 2 Cr App R 467 at 481 E.

¹³²[1983] 33 SASR at 193-194.

medical evidence is, of course, relevant to findings as to the risks that reside in or are a result of recommended surgery or other treatment. It will also have a bearing on their materiality but this is not a question that is to be concluded on the basis of expert medical evidence alone. The issue under consideration is a different issue from that involved where the question is whether the doctor carried out his professional activities by applicable professional standards. What is under consideration here is the patient's right to know what risks are involved in undergoing or foregoing certain surgery or other treatment."¹³³

In other words, *the courts* will judge what a patient has a right to know. All three cases discussed above can be interpreted as a claim to 'turf' by judges, or alternatively, a restatement of the division of labour as regards medical negligence litigation. Expert testimony is indispensable in cases of medical negligence. A judge needs to know what the risks are. He also needs to be informed as to the likelihood of those risks occurring. Unless he is blessed with divine inspiration, it is doubtful whether a judge would have this sort of knowledge at his fingertips. To say that allowing expert medical evidence to determine the materiality of risks would be handing over to the medical profession the entire scope of the duty of disclosure displays an understanding of the role of experts in a democratic society which can be regarded as both poor and outdated. The issues raised by modern medicine are complex and inevitably those raised by modern medical research must be equally difficult to unravel. They cannot, however, be viewed in isolation.

"As economic and public operations become more complex, it is necessary to unite varying skills, different experience, different education, resulting specialization and different degrees of intelligence, or, at a minimum, its confident outward expression." ¹³⁴

2.9. CONCLUSION

¹³³(1980) 114 DLR (3d) at 13.

¹³⁴See Galbraith, fn 19 above at 65.

Whereas applying the methodology of the natural sciences to medicine met with great resistance,¹³⁵ there was no stopping the 'new scientists' once the resistance was overcome. Standard scientific reasoning was imported into the medical sciences lock, stock and barrel. The shortcomings of the model, where medical research is concerned, is that it does not encourage scientists to recognise the humanity of the objects of research; it does not encourage them to enter into a dialogue with the research subjects or even those outside the scientific community.

Research subjects as well as the rest of the community must have the opportunity to participate in the medical research debate *as of right* instead of on an *ad hoc* basis. Public dialogue must be institutionalised within democratic structures. The medical research process should be structured in such a way as to ensure the 'fair equality of involvement' or at least equality of opportunity to get oneself involved in the politics of the medical research process if one so chooses.¹³⁶ Experts and the public must co-operate in ascertaining principles for medical research.¹³⁷ The medical research debate should be constituted of individuals who, as Thomas Paine envisaged, operate on the basis of a compact with *each other*.¹³⁸ This entails dispensing with traditional prejudices which exist among the professions and the public in favour of dialogue. The law has a part to play in *facilitating* dialogue. The question with which we are faced is whether legal reasoning in the medical research debate should be based on confrontation or mediation.

¹³⁵...[the] struggle between the new science and the old learning was the general background to the controversies over anaesthesia, even as late as the 1870s, antisepsis. But the practice of medicine was only gradually affected by new scientific ideas and scientific ways of thinking; after all, the leading members of the profession in the 1830s had received their education in the eighteenth century and few of those who were most prominent in the 1870s had graduated later than 1840. Most doctors before 1850, and many as late as 1870, it would seem, simply did not observe or think scientifically". See Youngson, A J *The Scientific Revolution in Victorian Medicine* (1979) at pp 16-17.

¹³⁶See, for example, MacCormick, fn 43 above at 142.

¹³⁷See, for example, Habermas, fn 3 above at 351.

¹³⁸Paine T *Rights of Man* (1985) at p. 70.

CHAPTER THREE

MEDICAL RESEARCH AND LEGAL REASONING: INFORMED CONSENT

"...analysis of legal and moral reasoning cannot be pursued in terms of stable and fixed conceptual standards. Such analysis requires constant reassessment not only of the subject matter of analysis - legal and moral reasoning - but also of the fluctuating standards in terms of which investigation must necessarily proceed. It is though we were trying to measure an object which changes size by employing a shrinking or expanding yardstick. This state of affairs evidently requires that equal attention be given both to theories of reasoning and to concepts of logic and rationality in terms of which they are discussed. We might otherwise be employing obsolete critical standards."

Gidon Gottlieb¹

INTRODUCTION

The legal reasoning which lies behind the control of medical treatment has been extrapolated to medical research involving human subjects. This may be inappropriate given that the former is based on the medical negligence model, an "after the fact" approach. Medical research should be looked at prospectively. Tort actions are based on obligation. Consent based actions, on the other hand have evolved as a rights issue. While it is true to say that this applies to all three legal systems under consideration, they are, however, based on different principles, a subject to which we will return later. A feature which the systems share is that research subjects only have a voice in the event of injury thereby amplifying the prevailing view of them as victims.² This is a consequence of medical negligence being fault based. The purpose of this chapter is to consider alternative approaches.

Achieving a consensus view of medical research implies involving *all* the parties in the research process to take part in the discussion. However, a common denominator of the

¹*The Logic of Choice* (1968) at 15.

²See for example, Vikenty Veressayer's book which referred to the research subjects mentioned as the "victims of science". *Memoirs of a Russian Physician* (1901 Linden (tr)). As reproduced in part in Katz, *J Experimentation with Human Beings* (1972).

process in all three jurisdictions under examination, is that certain parties are protected at the expense of others. It has been argued, for example, that research subjects do not have a voice;³ I do not believe that this is entirely true. The researched upon do have a voice but it is the voice of the law as articulated through the language of rights,⁴ the current application of which, as has already been said, means that their voice is heard only when things go wrong. To this extent, the language of rights is multifocussed as, whilst appearing to empower the patient, it serves the ends of other groups such as insurance and pharmaceutical companies - and lawyers.

3.1. CONSENT - INTERNATIONAL CODES

The Nuremberg Code (1947) provides that, "*The voluntary consent of the human subject is absolutely essential.*" The absolutist nature of the Code is understandable given the historical context in which it was developed;⁵ it is, however, detrimental to furthering a consensus for it gives rights to the research subject over and above other parties - and this could paralyse or atrophy the research process. The pragmatism which was introduced by the Declaration of Helsinki was inescapable in view of the overpowering need to carry out research. However, it gives rise to a tug of war between the professions - in this case, between doctors and lawyers. Helsinki, it must be remembered, is made up of guidelines prepared by and for the medical research profession.⁶ The Nuremberg Code arose from the judgment of the Nuremberg trials;⁷ it is judge made - and so too is the doctrine of informed consent.

³See, for example, Faulder, C *Whose Body is It ?* (1985).

⁴See Herxheimer, A 'The Rights of the Patient in Clinical Research' (1988) *Lancet* 1128.

⁵See Annas, G J and Grodin, M A (eds) *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation* (1992).

⁶See Herxheimer, fn 4 above at 1128.

⁷*Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council law 10*, Vol. 1 (Washington, D. C.: Superintendent of Documents, U. S. Government Printing Office, 1950); Military Tribunal, Case 1, United States v. Karl Brandt et al., October 1946 - April 1949, pp. 27 - 74.

3.2. INFORMED CONSENT

The greatest modern change in medical practice has been founded on the doctrine of informed consent which many physicians like to think is a myth.⁸ This is probably because the concept was not introduced by the medical profession. The school of law was responsible for its implantation and it was the lawyer, both practitioner and academic, who nurtured its gestation. It is arguable that the concept has been hijacked by the lawyers as a means of retaliation for what is seen as decades of hegemony by the medical profession.⁹ To this extent, informed consent is a battleground on which the law and the doctor confront each other.¹⁰

Several consequences have been identified which include the erosion of trust, the alienation of the parties involved,¹¹ the use of consent as a defence weapon¹² and so on.

⁸See Beecher, H 'Consent in Clinical Experimentation-Myth and Reality' (1966) 195 JAMA pp. 34-35. and also Silverman, W A 'The myth of informed consent: in daily practice and in clinical trials.' (1989) 15 J Med Eth at 6.

⁹Indeed, the "law is currently making its presence felt" as the health care delivery system in the United Kingdom is reorganised within a legislative framework over tighter management and greater medical accountability. The use of declarations has increased as has the recourse to litigation which has engendered a climate of distrust. See Teff, H *Reasonable Care: Legal Perspectives on the Doctor / Patient Relationship* (1994) at p. 33. Some commentators believe that the law in fact entrenches the medical hegemony. See Montgomery, J 'Medicine, Accountability, and Professionalism' (1989) 16 J Law & Soc 318.

¹⁰"...it should not be surprising that on the battlefield of informed consent, law and medicine glare at each other over barricades of suspicion and misunderstanding." See Piper, A 'Truce on the Battlefield: A Proposal for a Different Approach to Medical Informed Consent' (1994) 22 J Med Eth at 301.

¹¹Although see the report of pilot mediation schemes being introduced in two English regions for medical negligence actions in (1995) 109 Bull Med Eth 2. See also Hansard, 18. 5. 95, Col 344. Mediation schemes (*Gutachterkommissionen / Schlichtungsstellen*) are widely used in Germany in relation to medical litigation. See Giesen, D 'Gutachterkommissionen und Schlichtungsstellen, Anspruch, Praxis, Perspektiven' in *Arbeitsgemeinschaft Rechtsanwälte im Medizinrecht* (ed) *Gutachterkommissionen und Schlichtungsstellen* (1990) at p. 77 and also LG Dortmund, 3 Feb 1987 JZ 1988, 255.

¹²"...by analysing the doctor's need to obtain consent solely as a mechanism by which the doctor obtains her or his defence to an action for assault or trespass to the person. But that surely cannot be right. The effect of consent is indeed to provide a defence, but that is not its purpose. Its purpose is to protect the patient's right of choice, or as it might be put, the patient's autonomy. The only point in a doctor asking a patient to consent to proposed treatment is to give the patient the opportunity to say no, that is to refuse." See McK Norrie, K 'Medical Treatment of Children and Young Persons' (1994) 57 Arch Recht-und Sozialph/Beiheft 109 at 113.

These, however, are negative results which do not ask the question - who benefits? It is my opinion that while neither the patients nor the doctors nor medical practice are the beneficiaries, lawyers do not do too badly out of the consequences. The drug companies also remain conveniently out of the 'big picture'; doctors are convenient scapegoats.¹³ This is also the case in medical research. The blame for experiments carried out during the Third Reich has, more often than not, been allocated to the physicians who conducted the research without regard to the institutional framework which enabled and, indeed, encouraged research of this nature to be undertaken. However, as has been stated by one commentator, the Holocaust,

“...did not just, mysteriously, avoid clash with the social norms and institutions of modernity. It was these norms and institutions that made the Holocaust feasible.”¹⁴

In the American case of *Tuskegee*, for example, attempts were also made to shift full responsibility to the physician who directed the experiment. Even so the government was conducting these experiments rather than protecting the citizens against them.¹⁵

3.3. THE PATIENT: RIGHTS - A COMPARATIVE VIEW

The development of patient rights was an American phenomenon, yet one which has been transplanted into both the United Kingdom and Germany. However, whereas measurement of the accountability of the medical profession by way of the rights discourse has been accepted universally, there are differing contexts in which these rights have been exercised; these contexts must be distinguished. In so doing, it is

¹³This is in tune with the NHS indemnity scheme as introduced in 1991 in Britain which provides economic advantages to the NHS but does not allow doctors to clear their name. See Brazier, M 'NHS Indemnity: The Implications for Medical Litigation' (1990) 6 PN 88.

¹⁴See Baumann, Z *Modernity and the Holocaust* (1990) at p. 87.

¹⁵See the remarks cited by Jones, J H *Bad Blood: The Tuskegee Syphilis Experiment* (2nd edn, 1993) which include those of a Public Health Service (PHS) official who was reported to have said that, "Whoever was director of the VD section at that time, in 1946 or 1947, would be the most logical candidate if you had to pin it down." See p. 8 et seq.

helpful to distinguish the systems by applying three models of rights; consumerist (USA), welfare / consumerist (UK) and self-determining / *Sozialstaat* (Germany). It follows that different outcomes arise from the models. The context of health care systems provide an invaluable insight as to the way patient rights are interpreted and qualified; a factor which deserves closer examination.

3.3.1. THE UNITED STATES (CONSUMERIST)

Informed consent is a product of the American constitution which explains why it is framed within the parameters of rights. The decision in *Cobbs v. Grant*,¹⁶ in which the patient's right to know was considered to override professional privilege to withhold information, illustrates the adversarial mood of the time which was fuelled by the consumer, civil and women's rights movements which flourished during the Sixties.¹⁷

Informed consent was first referred to, as a concept, in a 1957 Californian decision, *Salgo v. Leland Stanford, Jr., University Board of Trustees*.¹⁸ The court also referred to what it termed as "intelligent consent". It is unclear why "informed" replaced the word "intelligent" and some commentators have found this regrettable.¹⁹ Perhaps "informed" was perceived to be more egalitarian and to be free from any élitist connotations that the word "intelligent" might have. If this is the case, the hidden assumption is that intelligence is linked to an institutionalised, professional benchmark. This is a recurring issue; it may, for example, explain why it is that lay members of research ethics committees are traditionally chosen from 'the professions'²⁰ and why we

¹⁶502 P. 2d 1 (Cal. 1972).

¹⁷Annas, G and Miller, F 'The Empire of Death: How Culture and Economics Affect Informed Consent in the U.S., the U.K., and Japan.' (1992) 20 Am J L & Med at 363. See also Veatch, R A *Theory of Medical Ethics* (1981) at 47-49.

¹⁸*Salgo v. Leland Stanford, Jr., University Board of Trustees*, 154 Cal. App. 2d 560; 317 P. 2d 170 (1957).

¹⁹See Mason, J K and McCall Smith, R A *Law and Medical Ethics* (4th edn, 1994) at 237 - 238.

²⁰This is discussed in Chapter Five in relation to the selection of lay members of research ethics committees.

appeal to the intuitions of the professional classes.²¹ The preferred position is that a person does not need a university degree to be classified as intelligent.

The doctor / patient relationship in the United States is index linked to market forces which has turned patients into consumers;

“Historically, most Americans treated health care as a private commodity whose price, and therefore availability, is primarily determined by market forces. In such a context, the law not unsurprisingly places a high premium on information disclosure by physicians. Personal autonomy-an individual’s power to choose among medical options-enjoys its most zealous protection under U.S. jurisprudence. The dominant U.S. version of informed consent is grounded on principles of patient/consumer autonomy, and seems to enhance market choice.”²²

The standard for disclosure is high - it must be full and frank. This requirement is reinforced by a greater awareness of patient rights in which the media play an important part - witness the furore which was caused by revelations concerning experiments conducted during the Cold War. Similar disclosures in the United Kingdom have met with a relatively muted response.²³

3.3.2. THE UNITED KINGDOM (WELFARE / CONSUMERIST)

Patients’ rights in the United Kingdom are not anchored in the constitution,²⁴ they evolved from the common law so as to remain in tune with the consumerist and women’s movements of the late sixties.²⁵ The scale of these movements, however, is not comparable to that in the United States. It is also arguable that the impact of an American export, was limited; despite the introduction of the citizens and patient’s charters, which supposedly uphold the rights of patients,²⁶ the doctrine of informed

²¹This is dealt with in further detail in Chapter Four at Section 4.2.1.

²²Annas and Miller, fn 17 above at 358.

²³See Pappworth, M *Human Guinea Pigs* (1967).

²⁴See McLean, S A M A *Patient’s Right to Know* (1989) at 22 - 25.

²⁵Faulder, fn 3 above at 19.

²⁶Although the point has been made that the Citizens’ Charter has redefined the citizen as a customer which, “... implies that members of the public should be content to choose from products or services

consent has no place in either English or Scots law.²⁷ This has led to the criticism by some commentators that the so-called rights are rhetorical rather than real.²⁸

The majority of health care in the United Kingdom is publicly financed; there is no contract between the doctor and the patient. As outlined above, the requirements governing disclosure are less explicit.²⁹ Patient rights have been developed alongside the evolution of the welfare state which has transformed the doctor / patient relationship into a partnership in the health care enterprise.³⁰ It is, however, an unequal partnership, the nature of which is dictated by the way the health care service is provided. Despite the appearance to the contrary, an element of gratitude is inherent in British medicine which, until 1948, had been concentrated in voluntary hospitals which had charitable status. This promoted an element of gratitude on the part of patients. The integration of these voluntary hospitals with teaching hospitals meant that many of the caring doctors were also academics. This gave rise to the opportunity for patients to be used as teaching or research material; in short, they were “willingly captive”. The circumstances surrounding patients’ care provided fertile ground upon which patients might want to give something in return for the care they were receiving, a *quid pro quo*, so to speak. The major consequence of the social revolution of 1948 was that patients were now being hospitalised as of right - and this altered the whole concept of the delivery of health care. The social dimension to health care was, however, still anchored in the harbour of gratitude.³¹

provided by others, and have no role in determining what those products and services should be or how they should be delivered.” See Stewart, J, Kendall, E, Coote, A *Citizens’ Juries* (1994) at 3.

²⁷*Sidaway v. Bethlem Royal Hospital and the Maudsley Hospital* [1984] QB 493 per Dunn LJ at 517. See also *Re T* [1992] 3 Med L R. 306 at 313 and *Moyes v. Lothian Health Board*, 1990 SLT 444 at 449. The standard for disclosure is provided by current accepted practice. See *Bolam v. Friern Hospital Management Committee* [1957] 2 All ER 118, [1957] 1 WLR 582.

²⁸See Teff, fn 9 above at 237.

²⁹See Robertson, G ‘Informed Consent to Medical Treatment’ (1980) 97 LQR 102 and Annas and Miller, fn 15 above at 359.

³⁰Kennedy, I ‘The Patient on the Clapham Omnibus’ in Kennedy, I (ed) *Treat me right: Essays in Medical Law and Ethics* (1988) at 175.

³¹Which some have suggested is to do with the concept of original sin which is inherent in British society. See Klein, R ‘Rationing Health Care’ (1984) 289 BMJ 143 who argues that we regard ourselves as fallen angels and feel that we do not deserve perfection. This is in direct contrast to the ‘perfection of man’ society which exists in the United States.

3.3.3. GERMANY (SELF-DETERMINING / *SOZIALSTAAT*)

The influence of a written constitution in the development of patient rights can be seen in Germany.³² Generally, the Basic Law enshrines the principle of the rule of law (*Rechtsstaat*)³³ and the principle of *Waffengleichheit der Prozeßparteien* or due process.³⁴ A case of vital importance arose in 1958³⁵ and was decided on the basis of the moral and legal right to self-determination as provided by Art 2 (2) of the Basic Law. It was held that information disclosure must be full and frank and must include an explanation of the risks which typically attach themselves to the proposed treatment.

The German model is based on universal health insurance which is indexed to employment; it is generally referred to as a compulsory insurance scheme.³⁶ The doctor / patient relationship is one of partnership and equality based in contract.³⁷ Patients, for their part, have followed the trend in becoming more critical.³⁸ Accordingly, medical litigation has increased which may have contributed to a greater level of accountability in the medical profession.³⁹ What distinguishes the German position is the framework within which the rights operate. Given the existence of a written constitution, the German position is, at first glance, comparable to the position in the United States. It

³²See Giesen, D 'Civil Liability of Physicians for New Methods of Treatment and Experimentation: A Comparative Examination' (1995) 3 Med L Rev 22.

³³Article 20 (1) of the basic law provides that the Federal Republic is a state based on the rule of law (*Rechtsstaat*) which is to be exercised within the parameters of the welfare state (*Sozialstaat*). See Stein, E *Staatsrecht* (14 edn, 1993) at § 24 IV at p. 204 et seq and also Appendix A. The concept of the *Rechtsstaat* has also been translated as a 'law-state'. See MacCormick, N 'Liberalism, Nationalism and the Post-sovereign State' (1996) 44 Political Studies 553 at p. 557.

³⁴BVerfG, 25. 7. 1979 2 B v R 878 / 74 BVerfGE 52, 131 (144). Generally, the right to a fair trial is guaranteed by Arts 2 Abs (1), (3), Abs. 1, 20 Abs. 3 of the Basic Law (GG).

³⁵VIZR 203 / 57 BGHZ 29, 46. There is a translation of this case in Markesinis, B *The German Law of Torts* (3rd edn, 1994) at 457-466.

³⁶See Moran, M and Wood, B *States, Regulation and the Medical Profession* (1993) at 10 and Webber, D 'The Politics of Regulatory Change in the German Health Sector' in Dyson, K (ed) *The Politics of German Regulation* (1992) at 209 and Hassenteufel, P 'The medical profession and health insurance policies: a Franco-German comparison' (1996) 3 Journal of European Public Policy 461.

³⁷See Giesen, D *Arzt Haftungsrecht* (4th edn, 1995) at 2.

³⁸See *Die Zeit* September 3, 1993 at p. 38; 'Wenn Ärzte pfuschen.'

³⁹Although this has, to a limited extent, contained by the presence of the expert and conciliation panels (*Gutachterkommissionen und Schlichtungsstellen*). See Giesen D, fn 11 above at 28-34.

differs, however, in that the Basic Law is committed to the concept of a *Sozialstaat* which gives a social dimension to the individualistic rights set out in the first nineteen articles.⁴⁰ The *Sozialstaat* is prescriptive to the extent that it implies legal obligations of the government.⁴¹ The system in Germany is more attuned to social justice, given the flexible and abstract nature of the concept of the *Sozialstaat* which enables it to operate in accordance with the ideology of a social market economy.⁴² The social justice ideology is, however, fighting for its survival as the true costs of reunification begin to mount up and Germany prepares itself to qualify for the stringent Maastricht criteria for monetary union.⁴³

Be that as it may, rights and obligations are vital as complementary within the medical research process. To avoid them atrophying into rhetoric, it is suggested that they are framed within a constitutional framework. This entails challenging the current model of legal reasoning, a consequence of which is that questions of medical research are umbilically tied to the concept of negligence.

3.4. THE COLLAPSE OF ANALOGICAL REASONING⁴⁴

Conflicts in research have consistently been based on medical treatment. The analogy is, however, inappropriate in view of the additional issues and interests which arise in research and which the treatment analogy hides from us.

⁴⁰For this section see generally Johnson, N *State and Government in the Federal Republic of Germany* (2nd edn, 1983) and Ogus, A *The Federal Republic of Germany as Sozialstaat: A British Perspective* (University of Manchester Faculty of Law Working Paper No. 3 June 1990).

⁴¹See arts 20 and 28 of the Basic Law.

⁴²“As the dominant ideology of the new Federal Republic became that of a “social market economy”, so the *Sozialstaat* could be identified as a corrective to the market processes, enabling the fruits of that process to be used for the protection of those unable adequately to prosper by it.” Ogus, fn 38 above at 6.

⁴³See for example *Der Spiegel* August 26, 1996 pp 26 - 28 and pp 78 - 84.

⁴⁴Term borrowed from Kingdom, E “‘Lawyers will Draft Anything’: Attitudes to Cohabitation Contracts’ (Occasional Paper No. 5 *Issues in Sociology and Social Policy*, University of Liverpool 1994) at 20.

The concern of this thesis is that the ethical issues raised by medical research are being debated within the restricted field of cause and effect. Their interpretation is largely in the hands of civil lawyers who are traditionally obsessed by the dual concepts of fault and the sanctity of property. As to the first, the general response to questions of consent within medical research is to apply the principles of the torts of battery and negligence in respect to disclosure. Proper disclosure is generally held to be "...a matter of law for the courts".⁴⁵ 'Sidaway Consent' has been applied to medical research of necessity - the reason being that there is no case law directly concerning research in the United Kingdom.⁴⁶ The trend can be seen in the main case governing consent to medical research - the Canadian case *Halushka v. University of Saskatchewan* - the ratio of which is also based on the treatment analogy despite the fact that that it was clearly a non-therapeutic situation. Thus,

"There can be no exceptions to the ordinary requirements of disclosure in the case of research as there may well be in ordinary medical practice."⁴⁷

The judge's basis for saying this is unclear. Whatever its basis, however, it is a retrospective analysis. In short, it is the product of a method of thought which revolves around problem solving based on past cases in which things have gone wrong. Questions of research, however, should also be considered *prospectively*.⁴⁸ The application of principles governing ordinary treatment is of limited use to the medical research model for the following reasons. First, litigation is adversarial and antagonistic; principles which govern medical research should result from mediation between the parties rather than confrontation. Secondly, it is questionable whether legal reasoning in the medical research debate is the appropriate standard given the restrictive view that it provides of the dynamics of research. The medical research process is characterised by

⁴⁵Kennedy, I and Grubb, A *Medical Law: Text and Materials* (2nd edn, 1994) at p. 1046. See also Giesen, fn 32 above.

⁴⁶See McHale, J 'Guidelines for Medical Research' (1993) 1 Med L Rev 180.

⁴⁷(1965) 53 DLR (2d) 431.

⁴⁸"...though the methods of casuistry have far more value than the common perjorative use of the term indicates, they are, none the less, radically limited so far as determining or questioning what those basic principles and their relative importance should be." Gillon, R *Philosophical Medical Ethics* (1991) at 19.

social and relational change which the law, as it is applied, fails both to recognise and to accommodate.

A brief case-study of a leading medical research case, the *Moore case*⁴⁹ illustrates the shortcomings of the current model of legal reasoning used in the debate. The main issue arising in the *Moore case* can be summarised in the question - to what extent, if at all, should donors of tissue be entitled to a part of the profit of a biotechnological product which has been engineered from the donor's tissue? The relevant legal academic debate has concentrated on the law of property,⁵⁰ at the expense of an analysis of the wider implications of the case. The fact that a patient's doctor set up his own company to manufacture pharmaceuticals using his patient's cells⁵¹ does not appear to have greatly concerned the protagonists of the main 'body as property' argument. This issue must, however, be addressed as it illustrates how the doctor / patient relationship alters within the context of research from that accepted as the norm in medical treatment. Medical research calls upon doctors to exercise numerous roles which include *inter alia* that of a healer, scientist, entrepreneur and politician; professional multiple personality disorder goes with the job!⁵²

Moore was really about the influence of the pharmaceutical lobby. Had the legal community drawn a parallel with the 'Tobacco War' which has been raging in the United States for years,⁵³ they might have been able to see the wider rationale behind the case. Taking on tobacco barons is as difficult as taking on the 'drug barons' of the pharmaceutical industry, both of whom are loath to part with profits. Given the link which has been proved between cancer and tobacco, and the responsibility which has

⁴⁹*Moore v. University of California* (1990) 793 P.2d479 (Cal.Sup.Ct.)

⁵⁰See Dworkin, G and Kennedy, I 'Human Tissue: Rights in the Body and Its Parts' (1993) 1 Med Law Rev 311, Dickens, B M 'The Control of Living Body Materials' (1977) 27 U Toronto LJ 142 and Magnusson, R 'Proprietary Rights in Human Tissue' in Palmer and McKendrick (eds) *Interests in Goods* (1993), Smith, A T H 'Stealing the Body and its Parts' [1976] Crim L R 622 and Skegg, P 'Human Corpses, Medical Specimens and the Law of Property' (1976) 4 Anglo-Am L Rev 412.

⁵¹As was aptly summarised by an article in the *The Washington Post Magazine* August 18th 1996 at p. 30.

⁵²This point in relation to the role of doctors has been made by Moran and Wood. See fn 36 above at 1.

⁵³See Kluger, R *Ashes to Ashes: America's Hundred-Year Cigarette War, the Public Health, and the Unabashed Triumph of Philip Morris* (1996).

been accepted by the giant tobacco companies for their 'killer' product, the Tobacco industry will lose millions.⁵⁴

The reason behind drawing a parallel between the negotiations surrounding the Tobacco War and the medical research debate is two-fold. First, both the tobacco and the pharmaceutical industry come under the jurisdiction of the Food and Drug Administration (FDA) which has regulatory powers. Secondly, and more importantly, is the fact that the tobacco negotiations, like the medical research debate, are dominated by certain groups that do not necessarily have society's best interests at heart: the industry and plaintiffs' lawyers;⁵⁵

"Rather than focusing on the regulation of tobacco, these players have put the bulk of their energy into developing a \$250 billion to \$300 billion fund that would compensate the industry's alleged victims. It's clear what they find appealing about such a deal: Plaintiffs' lawyers stand to make hundreds of millions; the industry wants to limit its liability and stabilize its stock valuations; and the state Ags will be able to crow about the billions they have won for their states."⁵⁶

Moreover, the parties who are at the negotiating table share a strong financial interest in striking a deal that focuses on compensating people for past loss as opposed to regulating the industry in the future. As we saw in Chapter Two, this short termist approach triumphs over long term preventive measures. Like the pharmaceutical industry, the tobacco giants will go a long way in order to secure their vested interests.⁵⁷

Had Mr Moore's claim succeeded, the pharmaceutical industry's generation of wealth would have had to have been spread to those without whom the enterprise would not

⁵⁴Under the agreement brokered between the industry and US states, cigarette makers will pay out \$368.5bn (£223bn) in compensation over the next 25 years in exchange for immunity from litigation - this excludes potentially ruinous punitive damages. Despite appearances to the contrary, however, the war has not been won. Profits will not suffer too greatly in view of the envisaged increase in cigarette prices. Indeed, the settlement has generated an increase in the tobacco companies' stock prices by up to 20 % and is set to rise higher, not least because the big three - Phillip Morris, RJR Nabisco and British American Tobacco - are enjoying strong growth overseas. See *The Financial Times* 21 June, 1997 and also *The Independent on Sunday* 22 June, 1997 at p. 12.

⁵⁵As regards the tobacco negotiations, the groups also include attorney's general from 24 states that have sued the manufacturers.

⁵⁶See *Business Weekly*, May 12, 1997 at p. 110.

⁵⁷See Chapter Two at Section 2.2.

have been possible - namely, the research subjects. The profits would have had to have been shared, although not necessarily equally. Mr Moore was little more likely to get money out of the company than to get blood out of a stone.

3.4.1. MR MOORE'S SPLEEN

Mr Moore, who was diagnosed as having leukaemia, was a patient at the University of California Los Angeles (UCLA) Medical Centre. In the course of his treatment, his doctor and his medical research colleagues developed a unique cell line using tissue obtained from his spleen. The University then patented and licensed the cell line together with the methods used to refine it, to several pharmaceutical and biotechnical firms. This was done without the knowledge of Mr Moore himself; he did not know that the research was being carried out and that specimens (e.g. blood), which were taken from him during the course of several hospital visits were used almost entirely for research purposes. Moore sought to bring an action for conversion of his spleen; the issue which had to be resolved was whether a donor of tissue is entitled to a part of the profit of a biotechnological product which has been engineered from a donor's tissue for commercial gain.

The Californian Court of Appeal held that Moore's action must succeed on the basis that ;

"Plaintiff's spleen, which contained certain cells, was something over which plaintiff enjoyed the unrestricted right to use, control and disposition. The right of dominion over one's own body and the interests one has therein, are recognised in many cases. These rights and the interests are so akin to property interests that it would be subterfuge to call them something else ."⁵⁸

Furthermore ;

⁵⁸249 Cal. Rptr 494 (1988) (Court of Appeal) at page 505.

“A patient must have the ultimate power to control what becomes of his or her tissues. To hold otherwise would open the door to a massive invasion of human privacy and dignity in the name of medical progress.”⁵⁹

On appeal, the Supreme Court of California held that Moore’s cause of action for conversion of his spleen must fail but that he did have a *personal* remedy for breach of the physician’s fiduciary duty and for lack of informed consent. Thus, the plaintiff was held not to have any *proprietary* rights but he did have a right to information.

The rationale behind the Supreme Court judgment upholds the principle that once a body part has been removed, it is obsolete and that accordingly, no property rights may be attributed to the origin of that property; nevertheless, it seems to be tempered by the Court’s apparent reluctance to extend the tort of conversion. It is apparent that the sale of human tissue was regarded by the court as being politically sensitive and that any extension to the doctrine ought to be effected by the legislature as a matter of public policy.

The majority of the Supreme Court also attached a great deal of weight to the possible impact that the judgment might have on the scientific community. In considering the community’s arguments that research and development in biotechnology would be hampered in the event of people having proprietary rights in their tissue, the court held ;

“ *unencumbered* access to human tissue for research is essential to progress and public health;...these sources must remain unencumbered, and medical researchers to be free to both combine materials with tissue taken from others, and dispose of the tissues, without answering to the person from whom the tissue was taken...[If the] plaintiff is permitted to have decision making authority and a financial interest in the cell-line, he would then have the unlimited power to inhibit medical research that could potentially benefit humanity. He could conceivably go from institution to institution seeking the highest bid and, if dissatisfied, claim the right simply to prohibit the research entirely.”⁶⁰

⁵⁹Ibid at page 508.

⁶⁰(1988) 51 Cal App.3d 1230 (Cal.C.A.). See also Dworkin and Kennedy, fn 50 above at 311.

The use of the word “unencumbered” is chilling and strikes a chord reminiscent of the bygone days of Nazi Germany. Broussard J, dissenting on the question of conversion, stated that ;

“... the majority analysis cannot rest on the broad proposition that a removed body part is not property but on the proposition that a patient retains no ownership interest in a body part once the body part has been removed.”⁶¹

From which the implication would appear to be that, whereas a donor of tissue might not have a right to a part of the profit in a biotechnological product, he might have an *interest*. This interest would not however, be a full entitlement to the financial profit, the justification being that Mr Moore was not entitled to a share in the profits since he had nothing to do with the actual work which was carried out on his cell line.

This reasoning is based on the doctrine of the labour theory of value which provides that the value of a product depends on the labour expended on it. The doctrine is attributed to the philosopher John Locke who stated that, “[t]he “labour” of [a man’s] body and the “work” of his hands...are properly his.”⁶² It is not possible nor, indeed, necessary to consider the minutiae of Locke’s so-called ‘labour theory’ of appropriation. In essence, however, the doctrine contains two elements.

The first is ethical in that it stipulates that the value of a product ought to be proportional to the labour expended on it. The second element is economic and provides that the labour should regulate the price. In conclusion, it is the labour which puts the difference of value on everything. Thus, scientists earn the property right by virtue of their labour and more importantly their knowledge. By implication, however, emanations of the mind are regarded as being worthy of property rights whilst the interests of the origins of the intellectual property are conveniently ignored. This is arguably yet another example of how the medical research process favours the professional élite and enables it to safeguard its interests at the expense of others.

⁶¹793 p . 2d (1990) 479 (Supreme Court) at page 501

⁶²Locke, J *Two Treatises of Government* (1924) [1690]], Book II, ch v, § 27.

Moore illustrates the lengths to which a “contented majority”, to use Galbraith’s term, will go to in order to protect what they see as *rightfully* theirs by recourse to a justification based on personal virtue, intelligence and effort. Thus,

“The first and most general expression of the contented majority is its affirmation that those who compose it are receiving their just deserts. What the individual member aspires to have and enjoy is the product of his or her personal virtue, intelligence and effort. Good fortune being earned or the reward of merit, there is no equitable justification for any action that impairs it - that subtracts from what is enjoyed or might be enjoyed. The normal response to such action is indignation or, as suggested, anger at anything infringing on what is clearly deserved.”⁶³

Thus, the wider rationale in *Moore* is based on the social justification based on expertise which was invoked to justify the pursuit and possession of wealth. The market for genetically engineered products is considerable. According to a forecast of the Commerce Department in the United States, the North American market is likely to amount to tens of billions of dollars by the 1990s.⁶⁴ In the European Union, it has been predicted that the expected turnover for biotechnology should reach 170 million DM as well as procure 2 million new jobs.⁶⁵ Claims by donors asserting a right to share in the profits gained from research and development using their cells could cost the industry millions of dollars. Several similar claims were brought after *Moore* but were settled out of court.⁶⁶

As well illustrating the fear of floodgates, *Moore* reaffirmed the political disenfranchisement of research subjects in the medical research process, an issue which has been taken up by Andrew Herxheimer;

“...clinical trials are planned, conducted, regulated, and used largely by medical and paramedical scientists in academic institutions, industry and government, with virtually no input from ordinary people.”⁶⁷

⁶³Galbraith, J K *The Culture of Contentment* (1995) at 18-19.

⁶⁴See Danforth, M T ‘Cells, Sales and Royalties: The Patient’s Right to a Portion of the Profits’ (1988) 6 Yale L & Pol’y Rev 179 at 180.

⁶⁵Meichsner, I ‘Die Claims werden abgesteckt’ *Die Zeit* May 19, 1995 at 33.

⁶⁶See Danforth, fn 64 above at 180.

⁶⁷Herxheimer, fn 4 above at 1129.

To reiterate the point made in Chapter Two, research subjects should have the right to participate in the politics of the medical research process if they so choose. It is necessary to secure political rights for research subjects as well as the rest of the community. A research subject, for example, should know what his rights are, should have a right to adequate information, a right to refuse information, to withdraw from the study at any time, a right to confidentiality and a right to a copy of the final report.⁶⁸ A Bill of Rights contains hopes and aspirations; it has the advantage of being prospective instead of after the fact. Moreover, it protects against the abuse of power and arbitrary decision-making. It sets standards of legitimacy and provides a framework within which socio/political dynamics can be resolved. As regards medical research, it is submitted that rights are only really effective if placed on a constitutional footing.⁶⁹

Moore says a lot about the medical research process. Not, however, if one concentrates on the emphasis on property rights as emphasised by the judges and commentators alike⁷⁰ which illustrates the fixation with civil law which pervades the legal reasoning in the medical research debate. It is submitted that a model of legal reasoning is needed which enables the interests which arise such as the power of knowledge, expertise, resources and language to be examined; the recognition and analysis of the power differentials demands close attention.⁷¹ Legal reasoning in the medical research debate

⁶⁸Ibid.

⁶⁹Concerning the issue of prospectivity, it is submitted that it should not, as it has been suggested, act as a substitute for ethical reasoning. See Fulford, K W M and Howse, K 'Ethics of research with psychiatric patients: principles, problems and the primary responsibilities of researchers' (1993) 19 J Med Eth 85 at 89. Regarding the point about constitutionalism see Preuß, U K 'Der Begriff der Verfassung und ihre Beziehung zur Politik' in Preuß, U K (ed) *Zum Begriff der Verfassung. Die Ordnung des Politischen* (Fischer: Frankfurt am Main, 1994) at p. 5 et seq for a modern interpretation of a concept over which much ink has been spilt in political theory. Rousseau, for example, writes in the *Social Contract* (Penguin: London, 1968), "Since no man has any natural authority over his fellows, and since force alone bestows no right, all legitimate authority among men must be based on covenants." (at p. 53).

⁷⁰Dworkin and Kennedy, fn 50 above.

⁷¹It is suggested that these forms must not be separated into different spheres in terms of importance but must be seen as a whole. See Bertrand Russell: "Like energy, power has many forms such as wealth, armaments, civil authority, influence on opinion. No one of these can be regarded as subordinate to any other, and there is no one form from which the others are derivative." See Russell, B *Power* (1938).

must be sensitive to the dynamics between the parties in the medical research process.⁷² Power is internal to the dynamics of the research process. It is an oversimplification to suggest that it is a static property which is held or exercised by individuals or groups;⁷³ it is, however, developed through interaction in a variety of relationships. The principles for medical research must not be discussed as though these relationships did not exist. As Simmonds has written;

“Moral and Political values cannot and should not be discussed in isolation from the institutions and social histories that shape them. What is required is a sensitive historical reconstruction,...which is itself a form of conceptual analysis”.⁷⁴

The legal reasoning in the medical research debate must be developed beyond its current state of suspended animation which entails freeing it from the intellectual shackles within which it has been restrained. In short, the medical research debate must come of age.⁷⁵

3.5. DETERMINISM AND THE MEDICO - LEGAL DEBATE

⁷²This is an adaptation of Habermas' early ideas in which he argues in favour of the need for law to emphasise the intersubjectivity of human action is. See Habermas, *J Strukturwandel der Öffentlichkeit* (1962) and *Zur Rekonstruktion des Historischen Materialismus* (1976). Similar arguments in favour of contextualisation are made by feminist legal theorists. In particular, see Gilligan, *C A Different Voice* (1982).

⁷³“...the major difficulty arises from the prevailing view that power in medical settings is a social fact, established a priori by the differential position of individuals or groups within social structures (e. g., patients and physicians). More like actors who have memorized and rehearsed their lines before a performance, participants are seen as bringing power with them to the health care encounter: differences in rights, duties, and obligations are known in advance. Any change in the script - for example, a physician's attempt to be primarily a listener or a patient's attempt to ask many questions - is viewed as exceptional and deviant.” See Treichler, P A, Frankel, R M, Kramarae, C, Zoppi, K and Beckman, H B ‘Problems and Problems: Power Relationships in a Medical Encounter’ in Kramarae, C, Schulz, M, O'Barr, W M (eds) *Language and Power* (1984) at p. 63.

⁷⁴Simmonds, N *The Decline of Juridical Reason* (1984) at p. 13.

⁷⁵Note that the same point has been made in relation to Medical Law, which, as it has been argued, should not remain polarised between civil, criminal and public law but should be developed along ‘intergrationist’ or interdisciplinary lines. In keeping with this position, the appropriateness of courts as the forum for matters of medical law has been questioned. See Taupitz, J ‘Medizinrecht vor dem Gerichten - Ein Blick in die ferne Zukunft’ ZRP 1997, 161.

In his Reith lectures in 1980, the aspiring Ian Kennedy laid the foundations of what might be called the 'let's get the doctors' ideology'. In effect, his invective took a possible consequence of medical paternalism and remoulded it into the definition of the concept.⁷⁶ This is not only unscientific but it involves disguising the polemicist in the seductive role of the scientist. By taking an inductive stance, Kennedy reached a determinist conclusion; moreover, he was advocating the law as an alternative model of expertise.⁷⁷ Kennedy's approach - which is, essentially, that by claiming the scientific high ground, the medical profession can, and does, manipulate its patients to the point of exploitation - fails to provide a framework within which the complexities of the doctor / patient relationship can be analysed fairly and understood properly. It is analogous to the belief that unethical research must necessarily follow from the practice of research; it may be part of the spectrum of medical research but it is not a necessary consequence. Kennedy's deterministic stance is shared by other commentators.⁷⁸ The "true function" of the law has been described as protecting "the vital interests of vulnerable patients";⁷⁹

"...the common law, existing first for the protection of our liberties, is also the protector of an ethics of medicine grounded in the concept of duty: the duty of care required of one professing - that is, offering to patients in their vulnerability - the skills of medicine."⁸⁰

⁷⁶Kennedy, I *The Unmasking of Medicine* (1981).

⁷⁷This is a phenomenon also recognised by Ulrich Beck; "Forms of 'alternative' and 'advocacy' science come into being that relate the entire 'hocus - pocus of science' to different principles and different interests - and therefore reach exactly the opposite conclusions. In short, *in the course of the scientization of protest against science, science forces itself to run its own gauntlet*. New public-orientated scientific experts emerge, the dubious aspects of the foundations of scientific argumentation are exposed with counter - scientific thoroughness, and many sciences are subjected through their applied practices to a 'politization test' of a previously unknown extent." See Beck, U *Risk Society: Towards a New Modernity* (1992, Ritter, M (tr)) at p. 161.

⁷⁸"The potential for medical paternalism is increased by the growing informational imbalance that exists between doctor and patient, extending the power of the former and the dependency and vulnerability of the latter. In the medical context, where individuals often make the most significant decisions of their lives, professional tradition and technological progress have combined to frustrate *any* notion of patient control." See Giesen, D 'From Paternalism to Self-Determination to Shared Decision Making in the Field of Medical Law and Ethics' in Westerhäll, L and Phillips, C(eds) *Patient's Rights - Informed Consent, Access and Equality* (1991) at 20. See also generally Giesen, D 'Legal Accountability for the provision of medical care: a comparative view' (1993) 86 *Journal of the Royal Society of Medicine* at 648.

⁷⁹Giesen, D 'Vindicating the Patient's Rights: A Comparative Perspective' (1993) 9 *J Contemp Health L & Pol'y* at 277.

⁸⁰Dunston, G R review essay in (1993) 19 *J Med Eth* 56 of Kennedy I, fn 76 above.

As a consequence, the patient is designated the role of a victim, an assessment which has been transplanted to the medical research debate;

“They [patients] are still mostly passive participants in trials, unwitting beneficiaries of the results, ignorant victims of the mistakes.”⁸¹

Victimology has a tendency to promote protective measures which may be self-defeating. In the current climate, those who seek to protect the research subject could well be accused of paternalism in that they not only seek to tell patients what they *ought* to feel but, in so doing, also credit them with little enough intelligence.⁸²

My position as regards medical research - and it is this which lies at the centre of my thesis - is that democratic structures are needed which will help us to ascertain the normative principles for medical research. This position is an application of Habermas' theory of discursive democracy.⁸³

Rights and obligations which arise in medical research must not be exclusively interpreted within the framework of the civil law but must be placed on a constitutional footing, as in the case of California, where rights for research subjects are enshrined in statute.⁸⁴ The statute provides that research subjects are given the opportunity to sign the 'Experimental Subject's Bill of Rights' before clinical research can take place. The individual must,

- a) Be informed of the nature and purpose of the experiment.
- b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
- c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

⁸¹Herxheimer, fn 4 above at 1128.

⁸²Although the tide may be changing. See Campbell, A V 'Dependency: the foundational value in medical ethics' in Fulford, K V M, Gillett, G J M (ed) *Medicine and Moral Reasoning* (1994) at 184-205.

⁸³As outlined in *Between Facts and Norms: Contributions to a Debate Theory of Law and Democracy* (1996, Rehg, W (tr)).

⁸⁴Calif. Health & Safety Code § 24172 (1978) in Myers, D *The Human Body and the Law* (2nd edn, 1990) at 247.

- d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
- e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
- f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
- g) Be given an opportunity to ask any questions concerning the experiment of the procedures involved.
- h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.⁸⁵

Research subjects must also be given a signed and dated copy of the consent form after the nature of the procedure has been explained to them and they have given their consent. The Californian statute further provides what information the consent has to include in order for it to be valid.⁸⁶ Disclosure resembles the standards set by the federal Food and Drug Administration which require *inter alia*,

- 1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purposes of such procedures, drugs, or device. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of such experiment shall be informed as to whether they will actually be administered or dispensed a placebo.
- 2) A description of any attendant discomfort and risks to the subject reasonably to be expected.
- 3) An explanation of any benefits to the subject reasonably to be expected, if applicable.
- 4) A disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
- 5) An estimate of the expected recovery time of the subject after the experiment.
- 6) An offer to answer any inquiries concerning the experiment or the procedures involved.
- 7) An instruction to the subject that he or she is free to withdraw his prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.
- 8) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.
- 9) The name of the sponsors or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any

⁸⁵Ibid.

⁸⁶Calif. Health & Safety Code § 24173 (c) (1978) in Myers, fn 84 above at 247-248.

under whose general aegis the experiment, to whom the subject may address complaints about the experiment.⁸⁷

While the Californian model comes many steps closer to providing a democratic framework for medical research, it does so only in the sense of establishing an obligation to inform research subjects regarding matters restricted to the trial and in particular matters relating to consent. Thus, the right to information is interpreted in an individualistic manner. A collective model for rights would, however, entail an emphasis on information being based on an exchange of ideas where research subjects as well as representatives of the community are consulted for their opinions, suggestions or complaints concerning the trial. An example of such a model is provided by the *Renault* cases, which concerned the closure of a plant in Vilvord, Belgium.

In this case, judges in both Belgium and France annulled the unilateral decision of the directors to close the factory on the grounds that they had failed to consult representatives of the workers before reaching the decision. In so doing, the judges were in fact applying a European Community directive which establishes an obligation to create a European Work Council or a "procedure in business with a community dimension and groups of business with a community dimension for informing and consulting workers".⁸⁸ Renault had in fact implemented the directive before it was implemented into French law. The judge in the Belgian case cancelled the decision and held that the employers must start negotiations with the Work Council.⁸⁹ In particular, the Council must be given the opportunity to give an opinion regarding re-employment and retraining. The judge in the French case went even further by ordering an interdict forbidding closure of the plant until conciliatory and consultatory meetings had been held with the Work Council.⁹⁰ A plethora of issues arise as a result of the decision which can not be discussed here; however, for the purposes of the present discussion, the *Renault* cases illustrate the importance of providing the opportunity to participate in

⁸⁷40 Fed. Reg. 11, 854, § 46. 3 (c) (1975) in Myers, fn 84 above at 245-246.

⁸⁸See 94/45/CE of 22nd September 1994.

⁸⁹Case 18 / 97, Decision of the 3rd of April (unreported).

⁹⁰Case 97 / 00992, Decision of the 4th of April (unreported).

decision-making processes. It is an example of how procedural safeguards which are inclusive as opposed to exclusive can influence the substance of decisions.⁹¹ It is probably fair to say that the application of such a principle is now the norm in medical, therapeutic decision-making. The question then arises as to whether there is such a norm in relation to research. Since the answer in respect of the United Kingdom is almost certainly 'not in a universal context', we must, then, ask what should be the remedy? The purpose of this next section is to illustrate the merits of a structural - or what I refer to as a *procedural* - approach by considering the German model of care assistantship (*Betreuung*). I am interested not so much in the concept of the care assistant as in the framework within which he / she operates as the underlying rationale for the existence of the office.

3.6. DECISION-MAKING AND REAL DIALOGUE

Whilst the need for involving more parties in the medical-decision-making process has been acknowledged and promoted, little attention has been given to providing an adequate procedural framework in which these decisions operate. For example, the need to involve third parties, such as the family and friends, has been acknowledged in respect of those who are incapable of giving consent. Whereas the increasing trend to include more parties in the decision-making process is to be applauded, concern must be felt at our neglecting to consider what weight these opinions ought to have. We are failing to provide any procedural safeguards through which to realise a participatory ideal in medical decision-making.

As regards the regulation of medical research, the position in the United Kingdom in this respect is informal; the procedures used to regulate research are not the product of

⁹¹In the Belgian case, for example, the judge held that the Works Council must be consulted with regard to the impact of the decision on the level of the employment of personnel and the organisation of work which included considering revising the number of redundancies.

statute but are arise by way of official guidance.⁹² By contrast, the position in Germany is that research is strictly regulated by the Drugs Code (*Arzneimittelgesetz* - AMG). This has the effect that not only are research committees are thereby established by statute, but that in some cases, it is mandatory to consult third parties in relation to consent to clinical trials.

An advantage of the German model is that it provides a procedure according to which issues of consent can be resolved which includes the question of who should be involved in the decision-making process. In Germany, consent may be obtained from a third party in restricted circumstances. There are, however, drawbacks which include, for example, the fact that the final decision rests with the judge, which is, arguably, one of the model's weaknesses. We can look at the mechanisms available by way of the management of mental incapacity. The minutae of the position in the United Kingdom will be given in outline only because of the present "legal near-vacuum" which exists in relation to the regulation of medical research on mentally incapable people.⁹³ The position in Germany, by contrast, will be detailed given the presence of an intricate array of procedures as regards medical research and incapacity.

3.6.1. MENTAL INCAPACITY

It does not necessarily follow that mental incapacity renders people incapable of making choices. There is, however, a real danger that it is not always certain that they would be making the choices in their own interests.⁹⁴ Hence, there is a need to involve others in the decision-making process.

⁹²See Local Research Ethics Committees, Department of Health (1991) replacing HSC (15) 153 (1975) for England and Wales and Local Research Ethics Committees; Edinburgh (1992) replacing No. 1976 (GEN) 38.

⁹³Scot Law Com No. 151 at para 5.65.

⁹⁴McLean, S and Maher, G *Medicine, Morals and the Law* (1981) at 95.

3.6.1.1. THE UNITED KINGDOM

The position in England before the enactment of the Mental Health Act 1983 was that legislation allowed a guardian to be appointed to care for a mentally handicapped adult to consent to treatment on behalf of a patient just as a parent does on behalf of their child.⁹⁵ Section 8 of the Mental Health Act 1983 restricted the powers of guardians to such an extent that a guardian is now unable to consent to treatment of his 'adult ward' for any physical illness. Indeed, there is no such power available even to the court since 1959 when the *parens patriae* jurisdiction was withdrawn. In fact, it appears that adult guardianship was never widely used in England.⁹⁶

Be that as it may, the need to involve third parties in medical decision-making in relation to medical research has been recognised in the United Kingdom. Thus,

"...it would be good practice in most cases for the research worker to discuss the research with one or more close relatives, and discover their views. If there is no relative or the patient expresses the wish that his relative should not be consulted, it may be appropriate to consult an independent person who knows the patient well and will protect his wishes (for example a nurse). The choice of such a person should be approved by the Ethics of Research Committee. These people should attempt to form a judgment based on the patient's known previous opinions about research and on his recent behaviour, as to whether the patient would be likely to consent were he able to do so. Any patient who indicates refusal either in words or in actions should be excluded from the research whatever opinion is voiced by the others who have been consulted." ⁹⁷

The contribution of relatives has also been held to be desirable by the courts⁹⁸ as well as by the Law Commission.⁹⁹ Furthermore, the Mental Health Commission¹⁰⁰ has published a position paper¹⁰¹ concerning research involving patients detained under any

⁹⁵S. 34 (1) Mental Health Act 1959.

⁹⁶See Brazier, fn 11 at 95 and also Hoggett, B M *Mental Health Law* (3rd edn, 1990) at p. 280.

⁹⁷Royal College of Psychiatrists *Guidelines for Psychiatric Research Involving Human Subjects* (1990) 14 *Psychiatric Bulletin* 48.

⁹⁸See Lord Donaldson MR in both *Re J* [1992] Fam 33, 41 and *Re T* [1992] 3 WLR 782, 787.

⁹⁹See Law Com No. 129 at para 3.59 et seq.

¹⁰⁰The function of which is to monitor and to advise on the Code of Practice that the Mental Health Act 1983 required to be written.

¹⁰¹(January 1997) reproduced in (1997) 129 *Bull Med Eth* 8.

section of the Mental Health Act 1983.¹⁰² Its recommendations include *inter alia* that advice should be sought from third parties. Thus, for example, they argue in favour of seeking approval in writing of the patient's Responsible Medical Officer (RMO),¹⁰³ the desirability of consultation with the patient's nearest relative,¹⁰⁴ and the desirability of consultation with the patient's Approved Social Worker (ASW) and other members of the multi-disciplinary team.¹⁰⁵

Little attention, however, has been paid to the weight to be given to these ancillary opinions. The response of the Law Commission in England, for example, has been to focus on the definition of capacity. It has been proposed that the legal test for capacity should be clarified through legislation which would provide, *inter alia*, for supervision by a judicial forum.¹⁰⁶ The establishment of a supervisory body is a good idea but one may still ask - why must it be a *judicial* forum?

More recently, the English Law Commission recommended that non-therapeutic research involving the mentally incapacitated should be permissible subject to certain criteria. Thus, research into the incapacitating condition with which the participant is or may be affected could be lawful given that it has been approved by a Mental Incapacity Research Committee.¹⁰⁷ Two observations may be drawn from this. First, the proposed framework provides the individual affected with only a limited opportunity to have a say. Secondly, it does not allow *the rest of us* to have a say as to whether incapacitated individuals *as a group* ought to be included in medical research whether it be in general or in specific circumstances. It can, of course, be said that the committee is representative of the public and that, therefore, the committee model is a democratic model; procedures could be devised to ensure that it was speaking on behalf of the

¹⁰²This includes patients liable to be detained.

¹⁰³See fn 101 above at para 7.2 (ii).

¹⁰⁴Subject always to the patient's consent. See fn 101 above at para 7.2 (iv).

¹⁰⁵See fn 101 above at para 7.2 (v).

¹⁰⁶"There should be a judicial forum with a statutory jurisdiction: (1) to make orders approving or disapproving the medical treatment of incapacitated patients; and (2) to make declarations as to the patient's capacity or the scope of validity of the patient's own decisions." See Law Com No. 129 at para 4.4.

¹⁰⁷Law Com No. 231 at p. 228. See Draft Bill, clause 11 subsections (1) and (2).

public and that its concerns were not limited to those of a select élite. However, as will be outlined in Chapters Five and Six, experience shows that research ethics committees fall short of this ideal - and do so extensively. It is suggested that the Mental Incapacity Research Committee, were it ever to be introduced, would be subject to the same limitations as are research ethics committees.

3.6.1.1. (A) SCOTLAND AND THE TUTOR-DATIVE

The Scottish Law Commission has proposed that written consent must be given by the research subject's nearest relative which includes husband or wife, an adult child, a parent or a brother or sister.¹⁰⁸ It also considered the notion of an "independent other" - such as a senior nurse or social worker - as being appropriate.¹⁰⁹

In addition a mechanism is in place in Scotland whereby decisions can be taken on behalf of the mentally handicapped through the office of the tutor dative. This office is, admittedly, rarely used but, given its recent revival¹¹⁰ there is no reason why it should not be applied to *therapeutic* research. In the early case of *Dick v. Douglas*, the parents of a handicapped man were appointed tutors dative to their son and were given a list of express powers which included the right to consent to any health care that was in their son's best interests.¹¹¹ Thus, the ability to provide consent to treatment on behalf of handicapped adults exists in relation to treatment¹¹² and, by definition, therapeutic research is to be included under treatment. It is, however, very doubtful that the courts would extend the powers of the tutors dative to cover consent to non-therapeutic

¹⁰⁸ Scot Law Com No. 151 para 5.67 (d). Note that the Law Commission decided that the longer list of relatives used in s 53(1) of the Mental Health (Scotland) Act 1984 which includes *inter alia* grandparent, grandchild, uncle or aunt, and niece or nephew.

¹⁰⁹ Scot Law Com No. 151 para 5.72. See also Scot Law Discussion Paper No. 94 paras. 3.16-3.21.

¹¹⁰ See 1992 SLT 325 commenting on *Usher's CB Petitioner* (1989, unreported) and also *Queen's Petitioner* (1992, unreported). The use of the office has been confirmed in *Law Hospital NHS Trust v. Lord Advocate* 1996 SLT 848.

¹¹¹ 1924 SC 787. See also Ward, A 'Revival of Tutors Dative' 1987 SLT (News) 69.

¹¹² "...in Scotland, as in Canada, there is not the doubt that exists in England as to the powers to provide consent to treatment of handicapped adults." See McK Norrie, K 'Wrongful Life in Scots Law: No Right, No Remedy' 1990 JR 205 at 392.

research.¹¹³ By contrast, this would be possible in the more formal ambience of German practice.

3.6.1.2. GERMANY

Reconciliation with the past is an ongoing phenomenon in Germany.¹¹⁴ It has yielded concrete results which include the introduction of the concept of legal care assistantship.¹¹⁵ Applied to medical research, for example, incapacitated individuals may become involved in therapeutic research provided it is conducted with the agreement of a person's legal care assistant.

The benefits of this approach are, however, not as great as might appear at first sight. First, the final decision rests with a judge. Secondly, the concept was developed in the light of Germany's past and in relation to the issue of sterilisation.¹¹⁶

3.6.1.2.1. The Concept of *Betreuung* (Care / Maintenance)¹¹⁷

The *Betreuungsgesetz* entered into force on 1.1.1992 and provided that consent can be given on behalf of a person incapable of giving consent through a care assistant

¹¹³See Scottish Law Discussion Paper No. 94 para 3.57.

¹¹⁴See for example Sattler, K-O 'Aus der Geschichte müssen auch die Ärzte Grundsätze erwachsen' *Frankfurter Rundschau* October 21, 1996 and 'Das Gespräch: Das Dilemma der Medizin und der Umgang mit der Ratlosigkeit' *Frankfurter Rundschau* October 25, 1996 at 14 - 15 and Emmrich, M 'Die neue Ärzte-Generation bricht die Tradition des Schweigens' *Frankfurter Rundschau* October 26, 1996 at 1.

¹¹⁵See below.

¹¹⁶In Germany, the undertones of the past influence the ideological framework within which medical research is regulated. Non-therapeutic research involving the 'mentally incapable', for example, is treated with dogmatic revulsion. A perusal of the regulations which were enacted during the period of the Third Reich provide an informative background to this position. A 1933 regulation, for example, justified the sterilisation of individuals including schizophrenics, people suffering from manic depression, people who were born blind and deaf, people with severe physical and mental handicap and people who were born with Huntingdon's Chorea and alcoholics, the rationale being that these inferior (*Minderwertig*) or hereditary tainted (*erbliche Belastete*) individuals represented a burden to the rest of the population and would lead to the downfall of the German people *Gesetz zur Verhütung erbkranken Nachwuchses* (Vom 14. Juli 1933, Reichs-Gesundheits-Blatt 8 Jhrg. 1933 at p.622-624).

¹¹⁷All translations of the German terms from hereon are my own.

(*Betreuer*) where the individual can not deal with his own affairs. The reason for reforming the existing legal framework is that, as it stood, it placed a great emphasis on protection which, it was felt, undermined both the will and the identity of the individual. The concept of guardianship and curatorship did not give the incapax an opportunity to articulate his wishes, his concerns and his choices. It was therefore decided that the new law ought to promote minimal interference with the right to freedom and dignity of the individual and should uphold his right to have his say. It was further recognised that the language of the statutory scheme needed to be altered in order to incorporate and give effect to the policy change.¹¹⁸ Thus, the German model moved away from the concept of legal guardianship, with all of its over - protective connotations, towards an emancipatory concept of care assistance.¹¹⁹

In effect, the law places the care assistant in the position of a representative entrusted with, *inter alia*, the determination of residence, questions of property and medical treatment. The assistant's duties are divided into legal and quasi-legal duties; he is a judicial and an extra-judicial representative.¹²⁰ The input of people close to the individual who can testify as to his wishes, such as family and friends, is vital; the care assistant is not a confidante in that he cannot interpret the individual's likely intentions.¹²¹

3.6.1.2.2. Medical Research

The Drugs Code (AMG) provides that an incapacitated individual may be involved in cases of therapeutic research with the consent of the care assistant. The benchmark for the decision, relates to decisions concerning medical treatment, which a care assistant

¹¹⁸*Betreuung* was favoured above other concepts in the Civil Code such as *Beistandschaft* which refers to aid, assistance, support (§ 1685 BGB).

¹¹⁹An interesting parallel is the recent decision to change the name of the charity from "Scottish Council for Spastics" to "Capability Scotland". Capability Scotland was launched on April 25th, 1996. See Holmes George, D 'What's in a Name ?' in (1996) 10 *Catch-Up* at 16.

¹²⁰§ 1902 BGB.

¹²¹This is not clear from the text of the Act as *Betreuung* is often used in conjunction with the adjective *persönlich*, or personal which gives it a semblance of subjectivity which was not intended by the legislature. See FamRZ 1988 at p. 904.

may consent to according to criteria¹²² which include factors such as that the assistant must orientate himself according to the wishes of the individual and with regard to his welfare,¹²³ he must represent the wishes of the individual¹²⁴ and the treatment must contribute to the individual's condition or situation.¹²⁵

Generally, examinations, treatment and interventions may only take place with the individual's consent. The validity of the consent is not based on legal competence but varies according to his capacity for understanding. Certain measures can and must be invoked if the individual is incapable of consenting. He may consent if he has reached an agreement with his care assistant; if no agreement can be reached, the doctor must decide whether he is capable of understanding the nature of the procedure involved. Moreover, the permission of the Guardianship Court is needed for health examinations, medical treatment and medical interventions where there is a danger that the individual could die or suffer serious and long lasting medical damage.¹²⁶

Two comments follow. First of all, the involvement of the Guardianship Court suggests that the protective tenor of the regulations has not been entirely erased. Secondly, the danger referred to above is assessed both subjectively and objectively, using a provision of the Criminal Code as a benchmark.¹²⁷ There is a degree of pragmatism, however. Whereas heart surgery would necessitate seeking permission from the court, a mere tooth extraction would not. In the event of doubt, a physician can get advice from the court¹²⁸ or can obtain precautionary permission which is analogous to the use of declarations in England and Scotland.

¹²² § 1904 BGB.

¹²³ § 1901 BGB. See also O Palandt *Kommentar* Diedrichson, U (ed) (54th edn, 1995) Rn. 7 zu § 1901 BGB.

¹²⁴ § 1901 II 1 BGB.

¹²⁵ § 1901 III BGB.

¹²⁶ § 1904 S. 1 BGB.

¹²⁷ § 224 StBG.

¹²⁸ § 1908 i i. V. mit § 1837 I BGB.

The new law also reformed the procedure relating to care assistantships¹²⁹ as well as providing for supervisory bodies entrusted with the supervision of the procedure. (*Betreuungsbehörden*).¹³⁰

3.6.1.2.3. Procedure

A care assistant can be applied for or he can be ordered by a court. An application can be made in respect of physical handicap only if this handicap prevents him from exercising his will¹³¹ but can be made in respect of any person who is mentally incapacitated.¹³² The application must satisfy certain conditions¹³³ which include *inter alia* that the subject must have reached his majority and must be suffering from a psychological, mental or physical handicap. The degree of invalidity is not prescribed. It is enough to show that the individual cannot deal with his affairs in their entirety or partiality and this is assessed in accordance with the principle of necessity (*Erforderlichkeit*).¹³⁴

There are different forms of carer which include honorary carers (*ehrenamtlich Betreuer*), who are unpaid,¹³⁵ carers from welfare organisations (*Vereinsbetreuer*),¹³⁶ and carers who work for the care authorities (*Behördenbetreuer*).¹³⁷ Generally, however, care is free of charge. The court can, however, grant a maintenance order if the individual has sufficient funds.¹³⁸

¹²⁹FGG (§§ 65-69 "Betreuungssachen" and § 70-70n "Untersuchungssachen").

¹³⁰Article 8 of the Betreuungsbehördengesetz (BtG).

¹³¹§ 1896 I S. 3.

¹³²§ 1896 I S. 2.

¹³³§ 1896 - 1908 i BGB.

¹³⁴§ 1896 II S. 1.

¹³⁵§ 1897 I BGB.

¹³⁶§ 1897 II 1 BGB.

¹³⁷§ 1897 II 2 BGB. Welfare organisations and care authorities can also undertake to represent the individual. See §§ 1900 I BGB and 1900 IV BGB respectively.

¹³⁸§ 1836 I 2, 3 BGB. A professional carer must be paid a fee or approximately 20 DM per hour; in some cases, he may even receive a sum of up to 100 DM (§§ 1908 i i.V. mit 1836 II BGB i. V. mit § 2 II 1 Zu SEG). If the individual is without funds, the State pays (§§ 1836 II 4 i. V. mit 1835 IV BGB). Expenses may be reimbursed for a sum of up to 300 DM a year (§ 1836 a BGB i. V. mit § 2 Zu SEG).

The notion that the wishes of the individual are paramount is of major importance. Procedural safeguards are provided whereby he may propose a particular care assistant.¹³⁹ Furthermore, his wishes must be respected by his care assistant provided they do not conflict with his overall well-being.¹⁴⁰ The emphasis on the individual's right to self-determination is further illustrated by the right to apply for a reversal for the need for a care assistant, and the right to change the care assistant.¹⁴¹

The procedural safeguards as set out in the *Gesetz über die Angelegenheiten der freiwilligen Gerichtsbarkeit* (FGG)¹⁴² provide that the court must hear from the person affected. The final decision as to whether he or she is capable of giving consent, however, rests with the judge. His decision is aided by expert testimony (*Sachverständigengutachten*)¹⁴³ regarding the need for the intervention, the alternatives and the likelihood of damage. Furthermore, the spouse, parents, children, as well as any confidants must be consulted as regards the wishes of the individual.¹⁴⁴ The tenor of self-determination can also be seen in relation to provisions which apply if the patient is unconscious.¹⁴⁵ It has also been argued that documentary evidence will be accepted as to the nature of the individual's wishes.¹⁴⁶ The final decision always rests with one party. In practice, this is usually the doctor but the judge decides once the court becomes involved.

¹³⁹§ 1897 IV BGB.

¹⁴⁰§ 1901 II 1 BGB.

¹⁴¹§§§§ 1896 I, II, 1897 IV, III 1a, 1908 d II and 1908 b III respectively. Note that care comes to an end when the conditions become obsolete. See § 1908 d I 1 BGB.

¹⁴²§ 69 d I 3 FGG.

¹⁴³Note that the doctor and the expert witness must *not* be the same person.

¹⁴⁴§ 69d II 3 i. V. mit § 68a S. 3. 4 FGG.

¹⁴⁵Consent must be, if possible, obtained from the family or a carer must be ordered. If the intervention is urgent, then the defence of necessity may be relied upon. The wishes of the patient must be gauged which may be done by referring to the patient's will, discussions with his family and confidants. They may only offer advice; the final decision rests with the doctor. If the patient will be unconscious for some time, a carer must be ordered by the guardianship court. See § 69 f I FGG.

¹⁴⁶Thus, paragraph 1896 II 2 BGB - which provides that a care assistant need not be selected if the wishes of the person affected can be ascertained in an alternative manner - could be used. See NJW 1994, 753 (757).

In effect, the legal provisions establish and uphold the voices of those who are incapable of giving consent. Thus, an individual can take an active part in the care procedure despite his mental incapacity.¹⁴⁷ Moreover, the court must gain an impression of the individual¹⁴⁸ who can appear in court or may be visited at home. The court must appoint a procedural care assistant both to advise and to represent the individual throughout the course of the proceedings (*Verfahrenspfleger*).¹⁴⁹ This care assistant is independent insofar as he is not there to act as the court's mouthpiece.

While the German model is designed to give individuals affected by incapacity the opportunity to express their opinions, the court also gives other persons the opportunity to be heard. Thus, the spouse, the parents, children, and confidants may represent their views by way of written pleadings within two weeks of the decision.¹⁵⁰ Once the care assistant is selected, his duties must be outlined for a set period of time which may not exceed 5 years. An order can be made that the decision take an immediate effect if there is danger in the inevitable delays in the process.¹⁵¹ The procedure may take up to one month but can be speeded up in certain situations. The decision of the court may be appealed;¹⁵² the appellate court is the regional Court (*Land Gericht*)¹⁵³ where the individual must be heard again and evidence on the points of appeal must be gathered and assessed as necessary.¹⁵⁴

Supervising the entire procedure are the so-called care authorities which were established by article 8 of the *Betreuungsbehördengesetz*. They are both created by and are the responsibility of the *Länder*,¹⁵⁵ in practice, they are the local magistrates' court

¹⁴⁷ § 66 FGG.

¹⁴⁸ § 68 I 1 FGG.

¹⁴⁹ § 67 FGG. Although this is not necessary if the individual is represented by a lawyer or a social worker.

¹⁵⁰ § 68 I 1 FGG.

¹⁵¹ § 69a III 2 FGG. The decision usually comes into force once the guardian is informed (§ 69 a III 1 FGG.).

¹⁵² § 19, 20 FGG.

¹⁵³ §§ 19 II, 30 FGG.

¹⁵⁴ Expert testimony, however, does not need to be obtained again. Appeal from this court is heard by a further instance, the *Ober Land Gericht*. See §§ 27, 28 FGG.

¹⁵⁵ § 1 BtBG

or the juvenile court.¹⁵⁶ The duties of the authorities include advice and support for the care assistant as well as the Guardianship Court.¹⁵⁷ They also have the power to propose a person as a care assistant on application by the court.¹⁵⁸

There is some overlap between the duties of the care assistant and those who must be consulted in order to ascertain the will of the patient and this may lead to tension; professional medical opinion may also be at odds with either or both parties. The imposed dichotomous responsibility is only acceptable if all parties work together.

A mechanism must be in place to resolve any difficulties and, since the framework is part of a legal construct, the final decision must rest with the judge. This can be seen as a substantial drawback of the German model. Why, when we are increasingly persuaded to mistrust doctors, should we trust the courts? Is this an endorsement of the view that "Judges know best"? There is no doubt that senior judges with dominant personalities can and have influenced the overall relationship between law and medical practice - and they may well continue to do so. As Ronald Dworkin has written concerning the relationship between judges and democracy;

"Democracy does not insist on judges having the last word, but it does not insist that they must not have it."¹⁵⁹

Hence, the question is whether the influence judges exert over medical practice is disproportionate.¹⁶⁰ Anyone with a sense of history will know that we need to be wary of judges. The German experience teaches us that the German legal system was not a victim of national socialism but an accomplice.¹⁶¹ Lawyers and judges actively sought to

¹⁵⁶See Schwab, FamRZ 1990 at p. 684.

¹⁵⁷It is entrusted with the provision of advice and support of the carer (§ 4 BtBG), the provision of information and training (§5 BtBG), the suggestion and promotion of activities for the individuals cared for i.e. by charities and organisations (§6 BtBG) and it must support the Guardianship Court (§ 7 I, II, § 8 BtBG).

¹⁵⁸§ 8 S. 3 BtBG.

¹⁵⁹Dworkin is not specifically referring to judges and medical litigation. See Dworkin, G *Freedom's Law: The Moral Reading of the American Constitution* (1996) at p. 7.

¹⁶⁰See for example Mason, J K 'Master of the Balancers' 1993 JR 115.

¹⁶¹See for example Wapler, F, Knobelsdorf, A 'Funktion und Umwandlung der Justiz im Nationalsozialismus' (1996) 3 Forum Recht at 76-78.

promote the ideology of national socialism.¹⁶² Moreover, American judges engaged in similar activity in relation to experiments conducted during the middle of the Twentieth century, albeit, toeing another party line.¹⁶³ This is not to deny that both the German and the American medical professions were happy to co-operate in purifying the race in one way or another. In effect, we must be wary of not only of the law but of professionalism as a whole.

3.8. CONCLUSION

The model upon which the decision-making process of the research process is based ought to be egalitarian. This involves changing the point of departure so that principles are not established in relation to things going wrong; the result of this is that research subjects are only heard in a court of law or in the newspapers when unethical research comes to light. What is needed is prospective guidance on both sides so that the process is reviewed not just when things go wrong but, also, when things go right. This entails a change in attitudes which depends upon the generation of information which is relevant to the parties concerned; this should be readily available on a continuous basis - it could be realised by, for example, providing a data base for researchers and research subjects.¹⁶⁴ There would, of course, be relatively high set up costs which could well be met by the pharmaceutical companies themselves.

In summary: the research process needs an injection with democracy - a system is needed which gives people the opportunity to be involved. For example, rather than have a process which is based on absolutisms - such as blanket bans on certain forms of

¹⁶²See Müller, I *Furchtbare Juristen* (1989).

¹⁶³See Goldner, J A 'An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Professor Katz Seriously' (1993) 38 St Louis U L J at 63-134.

¹⁶⁴This has been done in the United States in the shape of the Cochrane Centre in Baltimore which, together with the National Institutes of Health (NIH), is co-ordinating the creation of a register of randomised controlled trials. See Munro, A J 'Publishing the findings of clinical research' (1993) 307 BMJ 1340 and also Herxheimer, A 'Publishing the results of sponsored clinical research' (1993) 307 BMJ 1296.

research - a system is needed which involves the people who can decide which forms of research are desirable and which are not. Procedures must be created which allow society to reflect again and again on these issues, a process which has been referred to as the 'self-referential character of democracy'.¹⁶⁵ The medical research debate must be based upon a model of *reflective constitutionalism*¹⁶⁶ under which the normative principles for medical research can be ascertained continuously as opposed to once and for all decision-making. A moral code for medical research is not envisaged. Instead, a method of reasoning which will facilitate ascertaining the principles for research is needed. Moreover, the medical research debate must be structured in the complementary fashion which Habermas has referred to as *democratic institutionalisation*, a concept which lies at the heart of his most recent social theory.¹⁶⁷

There are general issues to be resolved. First, we must decide who is to take part in the medical-decision making process and how much weight should be attached to their views. Secondly, the conceptual model needs to be developed which includes a contextual analysis and in which paternalism is redefined as having a spectrum of consequences, positive as well as negative. Thirdly, we need an appropriate forum within an institutionalised framework for the discussion to take place. Procedures ought to be devised whereby the questions raised by medical research are brought into the public sphere; we need a sounding board which includes developing networks of communication which will enable access to information and different points of view - by this, I mean an outlook which embraces diversity and does not dismiss it. Public dialogue must be institutionalised so that it can operate from within the medical research debate. The ethics of medical research is a realm over which the philosophers have

¹⁶⁵MacCormick, N 'Constitutionalism and Democracy' in Bellamy, R (ed) *Theories and Concepts of Politics: An Introduction* (1993) at p.144.

¹⁶⁶Cf Preuß, U K *Revolution, Vortschritt und Verfassung* (1992) and also Preuß, U K 'The Political Meaning of Constitutionalism' in Bellamy, R (ed) *Constitutionalism, Democracy and Sovereignty: American and European Perspectives* (1996) at 11.

¹⁶⁷I am indebted to Dr Gerard Delanty whose paper, 'New Conceptions of Radical Democracy: Habermas on Social Protest, The Public Sphere and Law' which he gave at the Faculty of Law at Edinburgh University on November 28, 1997 helped me to further my understanding of Habermas' theory of discursive democracy.

traditionally asserted sovereignty. The question which will be considered in the next chapter is whether this sovereignty should be lost or should it be pooled ?

CHAPTER FOUR

MEDICAL RESEARCH AND MORAL REASONING

“Im praktischen aber fängt die Beurteilungskraft denn eben allererst an, sich recht vorteilhaft zu zeigen, wenn der gemeine Verstand alle sinnliche Triebfedern von praktischen Gesetzen ausschließt. Er wird alsdenn so gar subtil, es mag sein, daß er mit seinem Gewissen, oder anderen Ansprüchen in Beziehung auf das, was recht heißen soll, schikanieren, oder auch Wert der Handlungen zu seiner eigenen Belehrung aufrichtig bestimmen will, und, was das meiste ist, er kann im letzteren Falle sich eben so gut Hoffnung machen, es recht zu treffen, als es sich immer ein Philosoph versprechen mag, ja ist beinahe noch sicherer hierin als selbst der letztere, weil dieser doch kein anderes Prinzip als jener haben, sein Urteil aber, durch eine Menge fremder, nicht zur Sache gehöriger Erwägungen, leicht verwirren und von der geraden Richtung abweichend machen kann.”

Immanuel Kant¹

“It is incumbent on moral theory to explain and ground the moral point of view. What moral theory can do and should be trusted to do is to clarify the universal core of our moral intuitions and thereby to refute value skepticism. What it cannot do is make any kind of substantive contribution. By singling out a procedure of decision-making, it seeks to make room for those involved, who must then find answers on their own to the moral-practical issues that come at them, or are imposed on them, with objective historical force. Moral philosophy does not have privileged access to particular moral truths. Philosophy can't absolve anyone of moral responsibility in the face of moral and practical issues of great complexity.”

Jürgen Habermas²

INTRODUCTION

The moral reasoning behind medical research is caught in the tension between abstract principles and concrete practice. This entails a clash of values and the question arises - can clashes be resolved by finding universals? Universality is a contentious issue whether we are speaking generally or in relation to medical research.³ The main

¹*Grundlegung zur Metaphysik der Sitten*, Weischedel, W (ed) (1996) at 31. See below for translation.

²*Moral Consciousness and Communicative Action* (1990, Lenhardt, C and Nicholson, S W (tr)) at 211.

³See Macklin, R 'Universality of the Nuremberg Code' in Annas, G J and Grodin, M A (eds) *The Nazi Doctors and the Nuremberg Code* (1992) at 240 - 257.

argument which is made against universality by the communitarians for example, is that the principles advocated are a reflection of western cultural values; thus, they can only have particular or relative value.⁴ In other words, universal validity is imperialism “dressed up as humanity”.⁵ Another criticism is that universal principles can not presume to cater for all eventualities, that they are blind to context and are the result of sterile formalism. In the light of these criticisms, how can there be any norms which have universal legitimacy?

If we argue that medical research is the responsibility of society, it is imperative that a universal position is adopted; this is the way to the abolition of privilege and discrimination in the medical research process. Moral reasoning must, therefore, be concerned with proceedings rather than with consequences - or alternatively, with procedure rather than with substance.⁶ The role of philosophers in the research debate is not to provide the public with answers but, rather, to develop a method whereby questions raised by research can be addressed by looking at the underlying principles. Accordingly, the purpose of this chapter is not so much to provide a moral code by which medical research should be undertaken as to consider the ethics of decision-making. The aim is to establish norms that can be universalised; this can only be achieved if the consequences of the general observance satisfy the interests of all those affected.⁷

⁴See Selznick, P ‘Personhood and Moral Obligation’ in Etzioni, A (ed) *New Communitarian Thinking: Persons, Virtues, Institutions and Communities* (1995) at p. 110.

⁵Alexy, R ‘Debate Theory and Human Rights’ (1996) 9 *Ratio Juris* 210.

⁶Whilst procedure is a universal, substance is subject to modification at a grass roots level.

⁷“Valid are exactly those action norms to which all those possibly affected could agree as participants in rational debates.” See Habermas, J *Between Facts and Norms: Contributions to a Discourse Theory of Law and Democracy* (1996) at 12.

4.1. PRINCIPLES

It is widely agreed that the practice of medicine is based on principles of which the four cornerstones are respect for autonomy, nonmaleficence, beneficence and justice.⁸ Medical research has similarly been based on principles running from the codes of Thomas Percival (1803) and William Beaumont (1883) to the treatise of Claude Bernard (1865).⁹ A modern day principled approach has been encapsulated in both the Nuremberg Code (1947) and the declaration of Helsinki (1964). The role of principles is to guide decision-making; sometimes, however, principles, or their interpretation, clash. How ought conflicts to be resolved?

A plethora of ethical issues arise as regards the ethics of medical research involving human subjects which include, *inter alia*, recognition of the end point of research,¹⁰ the use of randomised controlled trials,¹¹ the exclusion of women as research subjects, and whether the results obtained by unethical research practices ought to be used.¹² The way in which these questions are answered differs according to the standpoint adopted. For example, as regards the first issue, a scientist might maintain that research ought to be carried out until such time as it becomes statistically significant. A doctor, however, might maintain that the end point should be as soon as harm or good is intuitively evident, while a pharmaceutical company may wish to complete the trial as soon as the

⁸Cf Beauchamp, T L and Childress, J F *Principles of Biomedical Ethics* (3rd edn, 1989).

⁹See the code of Thomas Percival written in 1803 by an English physician, cited in Beecher, H K *Research and the Individual* (1970) at 218. See also Reiser A, Dyck A, Curran W (eds) *Ethics in Medicine: Historical Perspectives and Contemporary Concerns* (1977) at 18-25 and also Percival, T *Medical Ethics* (3rd edn, 1949) at 27-68. See also the code by William Beaumont in 1833 which is the oldest American document dealing with the ethics of human experimentation which is reproduced in part in Beecher (1970) at 219 and also Claude Bernard's principles laid down in 1865 in his *Introduction to the Study of Experimental Medicine* (1927 Copley, H (tr)) at 101-102.

¹⁰See 'Early announcements' (1993) 342 *Lancet* 1001 and 'On Stopping a trial before its time' (1993) 342 *Lancet* 1311.

¹¹See generally Faulder, C *Whose Body is it?* (1985) Difficulties arise in relation to the question of consent and as regards the control group to whom the placebo is administered. See the public reaction to the use of RCTs in 1983 in trials involving women who were at risk of conceiving children with spina bifida. See Brazier, M *Medicine, Patients and the Law* (2nd edn, 1992) at 424-425. See also Mason, J K and McCall Smith, R A *Law and Medical Ethics* (4th edn, 1994) at p. 358.

¹²See Post, S G 'The Echo of Nuremberg: Nazi Data and Ethics' (1991) 17 *J Med Eth* 42 and Godlovitch, S 'Forbidding Nasty Knowledge: On the Use of Ill-gotten Information' (1997) 14 *Journal of Applied Philosophy* 1.

drug can be released into the market without fear of litigation. The purpose of this next section is to discuss the extent to which different standpoints are reconcilable.

Contemporary approaches to health care ethics have an impact on the practice of health care professionals; there are, however, differences in the underlying professional objectives or standpoints.¹³ In a study conducted in a psychiatry ward, Robertson found that the doctors' main concern was how to solve clinical problems, to maximise the organic functioning of patients and to conduct research whereas nurses tended to be more concerned to maintain the daily care and to foster their independence. Hence, the doctors and nurses differed in the emphasis and interpretation as regards the principle of beneficence. This was also seen concerning the shared commitment to respect patients' autonomy; nurses, for example, tended to include the notion of independent abilities (eating, shaving and washing in patients with dementia) in their definition of autonomy.

A different approach to resolving conflicts of principle was also detected. Nurses were more likely to emphasise the respect for patients' autonomy at the expense of beneficence while doctors were more likely to emphasise beneficence over and above respect for autonomy. Different experiences lead to different priorities; but what happens when priorities conflict? There is clearly a need to develop a framework within which conflicts can be resolved and a consensus can be reached.¹⁴ Traditionally, conflicts between doctors and nurses would have been decided in conformity with established hierarchies within medicine. In the wake of Project 2000, however, and with the increasing recognition of involving nurses in medical decision-making,¹⁵ the hierarchical boundaries have shifted.

¹³Robertson, D W 'Ethical Theory, ethnography, and differences between doctors and nurses in approaches to patient care' (1996) 22 J Med Eth 290.

¹⁴"The whole issue of how to "balance" or "harmonise" or otherwise prioritise conflicting moral principles or values in particular cases - the moral meat of casuistry - is one that requires far more study than it is currently obtaining, either philosophically or empirically." See Gillon, R editorial (1996) 22 J Med Eth at 260.

¹⁵*Re C (a minor)* (1989) 2 All ER 782, per Lord Donaldson MR.

The implementation of 'Project 2000' which was regarded as a creative alternative to traditional nurse training, provides a useful illustration of how a decision-making process can become almost unworkable. Launched in 1991, the programme emphasised the importance of academic study as well as of clinical experience.¹⁶ In particular, one of Project 2000's pedagogical aims is to encourage nurses to question proposed treatments which may include the practices of medical practitioners - doctors as well as nurses. In practice, however, the experience has been that the theory has a number of shortcomings. Some Project 2000 nurses have tended to question doctors' decisions in the presence of the patient. There can be no doubt that the most worrying consequence of this is that the patient's confidence in the doctor may be affected, thereby undermining the doctor's authority. Essentially, however, the problem is that *someone has to decide*.

A consequence of the 'clawback' on professional autocracy which occurred in the United Kingdom during the 1980's is that there was a failure to implement commensurate procedural measures to ensure effective decision-making. The absence of procedures has undoubtedly hampered medical decision-making. Be that as it may, much time and effort was spent on making nurses or members of a patient's family feel that they were participating. But, whilst appearing to be inclusive, the effect of the change in rationale has been, in effect, exclusive.

The ethos of medical research is generally believed to be the 'turf' of moral philosophers or 'bio' or 'clinical ethicists'. Medical ethics arguably saved some strands of philosophy in that, with the birth of the medico-legal debate, philosophy suddenly became 'useful'. Its participants could claim that they did not fritter away their time and public money in wondering how many fairies can dance on the head of a pin but could serve a 'real' or 'practical' purpose.¹⁷ It is the distinction between 'phoenix' and 'useful' philosophy, or 'systematic abstract speculation for its own sake as against applicable techniques of

¹⁶See Jowett, S, Walton, I and Payne, S *Challenges and Change in Nurse Education - A Study of the Implementation of Project 2000* (1994) at 7.

¹⁷This is entirely in keeping with the current climate of inter-University competition where research ratings mean money and academics having to justify their existence almost continuously.

critical thinking'.¹⁸ The market for applicable techniques is considerable, as the plethora of Institutes for medical ethics¹⁹ and the proliferation of 'ethics by committee', such as the Human Fertilisation and Embryology Authority, testifies.²⁰ But, whereas the role of these committees is invaluable, they do not involve the general public.

4.2. METHOD: PHILOSOPHICAL TRADITIONS

4.2.1. THE PHILOSOPHER KINGS

There is a tendency among philosophers to view themselves as possessing a divine right to considering questions of ethics; this accords with the traditions of some schools of philosophy which hold that not all of us are qualified to participate in substantive discussions on norms. Take this section from the *Republic*, for instance where Socrates is talking to Glaucon.

“‘Well then,’ I said, ‘is there any form of knowledge to be found among any of the citizens in the state we’ve just founded which is exercised not on behalf of any particular interest but on behalf of the city as a whole, in such a way as to benefit the state both in its internal and external relations?’

‘There is.’

‘What is it, and where shall we find it?’ I asked.

‘It is the Guardians’ knowledge,’ he answered, ‘and is to be found with those we called Guardians in the full sense.’

‘And how do you describe the state because of it?’

‘I say it has good judgement and wisdom.’

‘And do you think that there will be more metal - workers in our state or Guardians in this sense?’

‘Many more metal workers,’ he said.

‘Won’t the Guardians, in fact, be far fewer in number than any other group with special knowledge and name?’

‘Yes.’

¹⁸Haldane, J review essay in (1990) 16 J Med Eth 52.

¹⁹These include the Institute of Law and Ethics in Medicine (University of Glasgow), the Centre for Medical Law and Ethics (King’s College, University of London) and the Institute of Law, Medicine and Bioethics (University of Manchester and University of Liverpool). In Germany there is the Centre for Ethics in the Sciences and Humanities (Eberhard-Karls-Universität, Tübingen).

²⁰Established by the Human Fertilisation and Embryology Act 1990.

'So the state founded on natural principles is wise as a whole in virtue of the knowledge inherent in its smallest constituent part or class, which exercises authority over the rest. And it appears further that the naturally smallest class is the one which is endowed with that form of knowledge which alone of all others deserves the title of wisdom.'²¹

The role of the Guardians as having 'good judgement and wisdom' and the reference to the class which exercises authority over the rest and which 'alone of all the others deserves the title of wisdom' assumes that certain people are blessed with higher insights. One is reminded of Brecht's play, *The Life of Galileo* in which the main protagonist, Galileo Galilei battles almost continuously against the tendency of scholars to dismiss the common man from debates regarding questions about the nature of the universe;

PHILOSOPHER: ...as a philosopher I ask this question - are such stars necessary ?
Aristotelis divini universum.

GALILEO: Can't we speak in the vernacular? My Colleague, Signor Federzoni, doesn't understand Latin.

PHILOSOPHER: Forgive me. I thought that he was your lens grinder.

ANDREA: Signor Federzoni is a lens grinder and a scholar.

PHILOSOPHER: Thank you my child. If Signor Federzoni insists -

GALILEO: I insist.

PHILOSOPHER: The argument will lose elegance. But it's your house.²²

This attitude still prevails. Consider, for example, two modern schools of philosophical thought, namely, positivism and deontology. The former provides that values are subjective and that therefore only instrumental rationality counts. In essence, norms can not be derived from facts. Take, for instance the early writings of Wittgenstein;

"I once wanted to include in the preface the statement that my book consists of two parts: of what is presented here, and of all that which I have *not* written down. And it is this second part that is important. For through my book, the ethical is circumscribed as it were from within; and I am convinced that it can *only* be *strictly* circumscribed in this manner. In short, I believe that by remaining silent I have defined what *many* people today *babble about*."²³

²¹Plato *The Republic* (2nd edn, 1982) Part Five [Book Four] 428 d-e at 198-199.

²²Brecht, B *The Life of Galileo* (1982, Brenton, H (tr)) at Scene Four at p. 28.

²³Quoted from von Wright, G H's historical introduction to the *Prototractatus* (1971) at p. 15 cited in Apel, K-O *Towards a Transformation of Philosophy* (1980, Adey, G and Frisby, D (tr)) at 234.

The aim of positivism, which is to develop an ethos which is scientific in the sense of being free of values, in effect, relies on a culture of experts.

“In general, one can assert that in all sectors of public life in Western industrial societies, *moral* justifications of praxis are being replaced by pragmatic arguments that can be provided by ‘experts’ on the basis of objectifiable, scientific-technological rules. The instrumental, technical part and the strategic part of praxis can be grounded by objective if-then rules that can be regarded as logical transformations of scientific law-like knowledge.”²⁴

The reliance on experts is also illustrated by the deontological school of thought which is defined as being based on the “...common moral convictions that most of us have.”²⁵

‘Most of us’ is, however, selectively defined;

“convictions of thoughtful and well-educated people are the data of ethics.”²⁶

The emphasis on ‘thoughtful’ refers to the intuitive method upon which deontology is based. The introduction of ‘well-educated’ is, however, troubling as it suggests that only well educated people have the ability to think about ethics. However, examples from both the Third Reich and from America exemplify the failure of the professional élites in this respect.

The importance of the intuitions of the educated can also be seen as applying to medical research. Henry Beecher concluded that the main method of the control of research should be anchored in the intuitions and the conscience of the medical researcher. His position as regards the ethics of research is characterised by excluding the public from the debate. For example,

“Complexities abound; these entail, not only scientific, but moral, ethical, and sometimes legal problems. The confidence of the public in those who engage in such experimental pursuits is indispensable. Only if the public can be assured that self-discipline and ethical study are the rule will the necessary confidence be maintained. Careless or misunderstood investigations can do

²⁴Apel, fn 23 above at 235.

²⁵Nicholson, R *Research Involving Children* (1991) at 64.

²⁶Nicholson, fn 25 above at 64.

incalculable harm to medical progress. It is our collective obligation as a profession to see that this does not take place.”²⁷

He believed that research subjects could be protected by the doctrine of informed consent in conjunction with research carried out by an “*intelligent, informed, conscientious, compassionate, responsible investigator*.”²⁸ This assumes that the investigator has received the necessary training on which to base these qualities.²⁹ Jay Katz developed this theory in terms of what he refers to as a ‘persistent educational effort’.

“Only a thoughtful and persistent educational effort, for which this volume seeks to furnish a set of materials, can bring about real change in long-standing practices and thereby give some meaning to the suffering of those who were harmed by human experimentation.”³⁰

Several observations may be made. First, both writers’ reforms take place within the medical community. It is, for example, arguable that Katz is blurring the distinction between education and information - simply adding a course in medical ethics to a medical school curriculum is not necessarily going to bring about a revolution in the ethical insight of medical students. Principles for medical research ought to be the product of reflection and not merely handed down through student generations.

“Professional codes of ethics are devices to which lipservice is paid in any number of cases while practice creates discretionary exceptions which are capable of swallowing the ethical principles say, of the Revised Declaration of Helsinki when the physician / researcher decides the occasion requires it.”³¹

²⁷Beecher, fn 9 above at 119.

²⁸Beecher, H K ‘Ethics and Clinical Research’ (1966) 274 New Eng LJ Med 1354 at 1360. [emphasis added].

²⁹“As I became increasingly involved in the world of law, I learned much that was new to me from my colleagues and students about such complex issues as the right to self-determination and privacy and the extent of the authority of governmental, professional, and other institutions to intrude into private life....These issues...had rarely been discussed in my medical education. Instead it had been all too uncritically assumed that they could be resolved by fidelity to such undefined principles as *primum non nocere* or to visionary codes of ethics.” see Katz, J *Experimentation with Human Beings* (1972) at ix and also Beauchamp and Childress, fn 8 above at 13.

³⁰Katz, fn 29 above at 4.

³¹Giesen, D *International Medical Malpractice Law* (1988) at 578.

Secondly, and more importantly, to leave the emphasis of the regulation of medical research to the conscience of medical researchers is to prohibit, or at least considerably restrict, the access of other parties to the decision-making process concerning principles for medical research.

This is amplified in the debate concerning the use of results of unethical research.³² Strictly speaking, the concept of deterrence dictates that the results ought never to be published. The results may, however, be of scientific value. Would it then be a case of the end justifying the means ? Without wishing to become embroiled in a substantive discussion, the issue has been largely resolved in favour of the value of knowledge. Henry Beecher, for example, argued that such data could be published with stern editorial comment despite expressly stating that he did not share this view.³³ A letter by Jay Katz appeared in the same issue of the Journal in which he favoured the publication of data “improperly obtained”, arguing that,

“Such an editorial policy would maintain the low visibility of ‘unethical experimentation’ and preclude not only review but also careful and constant appraisal of the conflicting values inherent in experimentation. Indeed, to make these problems even more visible and subject to our collective scrutiny, all clinical research papers submitted for publication should include in the section on *methods* a clear statement of how consent was obtained.”³⁴

The references to ‘careful and constant appraisal’ and ‘collective scrutiny’ hint at a regulatory model for medical research which is self-corrective - that is, control is exercised by the peers of the researcher. Thus, medical researchers are both participants and a legitimating agency for establishing objective criteria for its practice, an assessment

³²See Godlovitch, fn 12 above and also Angell, M ‘Editorial Responsibility: Protecting Human Rights by Restricting Publication of Unethical Research’ in Annas, G J and Grodin M A (eds) *The Nazi Doctors and the Nuremberg Code* (1992) at p. 277.

³³Beecher, fn 28 above at 1320. And further, “It is debatable whether such publication should or should not be carried out. I at least have the support of the parallel case of the United States Supreme Court in which the Mapp Decision held that evidence unconstitutionally obtained shall not be used in any judicial decision, however important it may be to the ends of justice.” Letters to the Editor in Reponse to Beecher’s Essay (1966) 275 New Eng LJ Med at 791. See also the concession offered by Mason and Mc Call Smith, fn 11 above at 364-365; “...the fact that children do not, for instance, now die from certain forms of hypothermia is best regarded as a monument to those who suffered and died to make it possible; if the material is used, they will, at least, not have done so in vain”.

³⁴See Katz, fn 33 above at 791.

that is advanced in Chapter Two.³⁵ The only critical, reflective relationship which aspiring medical researchers are encouraged to enter into is with their teachers. However, leaving the ethics of research to the *foro interno* of researchers themselves is not only exclusive but it is also too opaque. In other words, the ethical principles for medical research should not be the product of the researchers' private metaphysical deliberations. There is a lack of transparency which renders the deliberations virtually unexaminable. Moreover, we can not be certain of our intuitions.

As Onora O'Neill states,

"we are opaque to ourselves (as also to others) and may be unsure which principles govern our actions in any situation. We may hope that we are fundamentally honest, but be well aware that situations we have faced have been ones in which, as luck would have it, honesty was the best policy, so that we were never put to the test. All that we can do is try to ensure that we are honest on principle rather than by luck is to align our outward actions with those that would express a maxim of honesty in ways appropriate to each situation we face."³⁶

Thus, a criterion for identifying morally worthy actions is needed in view of our ability to present a case selectively;

"If we are unsure what the maxim of a given act is, we cannot be sure whether it is morally worthy. Despite their best efforts at principled and self-conscious action, agents are prey to self-deception and selective perception. This is not rare or exotic but commonplace - we are repeatedly tempted to ascribe maxims that place acts and agents in a more flattering or a more lurid light".³⁷

It is important to stress that I do not seek to undermine the importance of intuitions, which are, after all, the data of moral agency.³⁸ The ethos of medical research, however, anchors or abdicates, depending on whichever way you want to look at it, most of the responsibility to the consciences of a select few.

³⁵See Section 2.2.

³⁶O'Neill, O *Constructions of Reason: Explorations of Kant's Practical Philosophy* (1989) at 130.

³⁷O'Neill, fn 36 above at 130.

³⁸As McCall Smith has pointed out, "A moral intuition may be a useful signpost to the good and right, but moral action is most likely to ensue in circumstances where there has been some effort to engage in moral analysis". McCall Smith R A 'Committee Ethics ? Clinical Ethics Committees and their Introduction in the United Kingdom' (1990) 17 J Law & Soc 124.

“...the intuitive ‘simple conscience’ approach has its pitfalls; the right of each person to an opinion on any moral question is not being disputed. What is being disputed is the extent to which that opinion may be based on a just balancing of the various factors involved. Everybody has a right to express an opinion on a moral issue (such as the involuntary post-mortem harvesting of organs) but the moral weight of that opinion is surely going to depend on the extent to which its holder is aware of some of the sensitive issues involved (such as religious sensibilities, family feelings, and so on).³⁹

Individual moral responses are not being rejected; there should, however, be a process whereby moral responses can, as Mc Call Smith puts it, be “attuned to the situation”.⁴⁰ Moreover, there is a need for a wider base of intuitions for ethical decision-making beyond the intuitions of philosophers.

The difficulty is that such an élite group is able to hide its evaluative statements concerning research under a veil of assumed neutrality, the influence of which can be far reaching. Whilst principles for medical research appear to be neutral, they are in fact the product of or, at least influenced by, the evaluative perspective of the participants in the debate. The purpose of the next section is to consider the model of affected impartiality as a foundation for the ethics of medical research with the aim of advocating an alternative approach.

4.2.2. CONSIDERED IMPARTIALITY RECONSIDERED

In *Medical Research with Children: Ethics, Law and Practice*, Nicholson proposes two levels of moral or ethical thinking. The first level is based on the ‘practical’, deontological school of thought whilst the latter is based on a ‘higher, critical’ level of thinking which is utilitarian. Thus,

“We should have, and teach, and cultivate in ourselves, those intuitions and those intuitive principles whose general acceptance in the profession and

³⁹McCall Smith, fn 38 above at 127.

⁴⁰Ibid.

outside it will do the best, all in all, for those affected, considered impartiality.”⁴¹

We must, however, question how impartiality or neutrality is defined. In particular, is it the case that neutrality is defined with reference to the affected neutrality of the educated ?

The emphasis on ‘considered impartiality’ represents a strand of moral theory which in its modern format as been espoused by philosophers such as John Rawls whose theory of justice remains a basis for much medical ethical thought.⁴² Gillon has, for example, stated that,

“This process of dynamic moral “reflective equilibrium”...requires both philosophical reflection and theory on the one hand, and empirical observation of the facts - the facts of people’s considered moral judgments, attitudes and actions - on the other. Neither is supreme, both are essential. In the pursuit of such reflective equilibrium empirical studies into what people’s considered moral attitudes, actions and judgments are and their justifications for them, are of importance not just to health care ethics but to ethics in general.”⁴³

According to Rawls,⁴⁴ principles of justice are devised from a hypothetical original position in which individuals must imagine themselves as rational abstract, free and neutral beings - it is an exercise in “point of viewlessness” and intended to avoid any interest based decisions being reached. He advances the notion of people in the ‘original position’, or ‘POP’s, who are caught in a state of neutrality. These people do not know anything about themselves; they can not make any judgements in connection with how their decisions will affect them.

Rawls has been criticised from many quarters, notably by feminists and communitarians who argue that the original position is a typically masculine way of looking at the world

⁴¹Nicholson, fn 25 above at 70.

⁴²Gillon, fn 14 above at 261.

⁴³Gillon, fn 14 above at 260.

⁴⁴*Theory of Justice* (1971).

as separate from context, concreteness and relations to others.⁴⁵ Certain groups of people have been traditionally excluded as potential research subjects.⁴⁶ This arises, for example, in the predominant use of white males as research subjects who have been assumed to represent society as a whole.⁴⁷ Accordingly,

“Members of the dominant group making decisions in reliance on this norm may discount or be oblivious to the influence of their particular perspective. To the contrary, they see themselves as “objective,” and the existing social structure as “natural.”⁴⁸

According to Dresser, medical researchers have defined the white male as the normal, representative human being.⁴⁹ She suggests that physical differences between males and females or between whites and people of colour remain unacknowledged. Others who support this view further argue that this is due to the fact that the participants in the medical research debate is dominated by the white, middle class professional élites.

At the same time, one might ask whether this analysis is, itself strictly neutral - and there are good reasons to doubt its accuracy. In the first place, any research results which would be influenced by differing physiological responses would be condemned as useless by reviewers if it did not involve a mix of male and female subjects. Alternatively, it may well be that white, male volunteers are the easiest group to obtain. If, therefore, the end-point of the research was independent of such factors, the choice of subjects would not be exclusionary but would, rather, represent the fastest and most economical route to a result - which would be a laudable objective. In short, while it may be arguable that the dominance of white males within the research élite influences the choice of subjects, it may be, equally, the result of pragmatic and well considered selection.

⁴⁵Brown, B ‘Feminism’ in Bellamy, R (ed) *Theories and Concepts of Politics* (1993) at 166 and also McHale, J, Fox, M and Murphy, J *Health Care Law: Text, Cases and Materials* (1997) at pp. 119-130. See also Kymlicka, W “Liberal Individualism and Liberal Neutrality” in Avineri, S and De-Shalit, A *Communitarianism and Individualism* (1992) at p. 165.

⁴⁶A phenomenon which has been described as “Tuskegee Fallout”. See Dresser, R ‘Single, White Male for Medical Research’ (1992) Hastings Centre Report at 27.

⁴⁷Dresser, fn 46 above at 27.

⁴⁸Dresser, fn 46 above at 27-28.

⁴⁹*Ibid.*

Even so, there is little doubt that research into conditions which affect women only or predominantly - such as anorexia or osteoporosis - suffer in comparison with their counterparts in men whilst investigations into illnesses such as heart disease have been carried out almost exclusively on men on the assumption that women respond to treatment in the same way as do men.⁵⁰

As regards the role of female volunteers in medical research, for example, the prevailing hypothesis as regards drug trials provides that research into conditions which affect women more than men, such as anorexia and osteoporosis, has lagged behind whilst investigations into illnesses such as heart disease have been carried out almost exclusively on men; this is based on the assumption that women respond the same way to treatment as men. The FDA implemented a 'Womens' Health Initiative' which lifted the 16 year ban on including women of 'child bearing potential' in early drug trials.⁵¹ The new rules require drug companies to include a sufficient number of women subjects in their drug safety tests to assess whether drugs affect women differently from men.⁵² Moreover, there have been reports which have suggested that cancer funding favours women.⁵³ Be that as it may, the committee at the Institute of Medicine (IOM) in the United States which was commissioned to investigate the issue of the inclusion of women in clinical studies, comprised, the "usual mélange of biostatisticians and bioethicists, pharmaceutical executives and behavioural scientists, academics from medicine and law, experts in public health and in the clinical evaluative sciences, the

⁵⁰But those who accept the alternative argument outlined above would see this as a responsible distribution of resources in that men constitute the great majority of cardiac patients.

⁵¹To which *advocatus diaboli* might respond - why should researchers be compulsorily exposed to another thalidomide scandal ?

⁵²See the FDA *Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs* 58 Fed. Reg. 39, 406 (July 22, 1993) which was followed by the passage of the so-called "Revitalization Act of 1993" NIH Revitalization Act 42 U. S. C. A § 201 (West Supp. 1993) and the NIH *Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research* 59 Fed. Reg. 14508 (March 28, 1994) originally published at 59 Fed. Reg. 11146 (March 9, 1994). See also *The Times* August 2, 1993 at 4, 6 and 8.

⁵³Mihill, C 'Cancer funding favours women, says doctor' *The Guardian* October 6, 1994. It is as wrong, however, to disregard men in certain circumstances as it is to disregard women.

former director of the NIH Office for Protection from Research Risks, and the current director of Johns Hopkins' Centre for Clinical Trials."⁵⁴

The *Tuskegee* experiments illustrates this selectivity in the reverse way. Certainly black people were used as subjects but we can see them, here, as being selected as a group who were not 'normal' insofar as they were expendable. *Tuskegee* shook the trust of the black community, so much so that when the first reports of AIDS emerged in the 1980s, the community thought of it as part of a conspiracy to wipe out the black race;

"For forty years their government had withheld treatment from men with syphilis so science could learn more about the disease. Many of the men had died from syphilis, while others had gone blind or insane. Confronted with the experiment's moral bankruptcy, many blacks lost faith in the government and no longer believed health officials who spoke on matters of public concern. Consequently, when a terrifying new plague swept the land in the 1980s and 1990s, the Tuskegee Study predisposed many blacks to distrust health authorities, a fact many whites had difficulty understanding."⁵⁵

Several members believed that AIDS was a form of genocide whilst some believed that it was deliberately created in a laboratory in order to infect black people. Such beliefs were not limited to the lay public; many black health workers refused to dismiss these fears out of hand.⁵⁶ The consequences of this paranoia were tragic. Many black sufferers avoided medical treatment, ignored the advice to use condoms (believed to be part of a population control scheme) and refused the offers of clean needles (believed to be a plot by the government to encourage drug abuse among the black community). The policy makers either ignored or underestimated the impact which *Tuskegee* had had. It is hard to believe that *Tuskegee* would have occurred if the black community had taken part in the initial discussions concerning the experiments.

These examples - of women and the black community - show that even the most creative minds of the 'great and the good' cannot embrace all the intricacies which arise in a

⁵⁴Merton, V 'Review Essay: Women and Health Research' (1994) 22 *The Journal of Law, Medicine & Ethics* 272.

⁵⁵Jones, J H *Bad Blood: The Tuskegee Syphilis Experiment* (2nd edn, 1993) at 221-222.

⁵⁶See Jones, fn 55 above at 222 et seq.

pluralistic society.⁵⁷ Decision-making by disengaged atomists is ethically unacceptable. Moreover, we are quite unable to blot out the influence of experience.⁵⁸ Principles for medical research must incorporate experience; any attempt to reject it out of hand is illusory.

Impartiality *per se* is an acceptable concept - what matters is the way in which it is exercised and by whom. Impartiality must be exercised so as to give due regard to the needs of all those affected. This can only be achieved through a process of practical deliberation.⁵⁹ Illness is a great leveller; it touches upon people's lives in many spheres - including the 'micro domain' (family, marriage, neighbourhood), the 'meso-domain' (national politics) and the 'macro domain' (mankind).⁶⁰ The development of medical science belongs to humanity's common interests;

"...the results of science present a moral challenge for mankind. Scientific-technical civilization has confronted all nations, races and cultures, regardless of their group-specific, culturally relative moral traditions, with a common ethical problem. For the first time in the history of the human species, human beings are faced with the task of accepting collective responsibility for the consequences of their actions on a world-wide scale. One might expect that this obligatory collective responsibility corresponds to the intersubjective validity of norms or at least to the basic principle of an ethics of responsibility."⁶¹

A forum is needed in which researchers can be schooled to become self-critical as Beecher and Katz suggest but one also in which the intuitions of researchers can be informed by the public so that they, together with policy makers, are not blind to the experience of others. What we need is to uncover the correct approach. Kantian philosophy, as transformed in the light of the last centuries, can provide a basis for the search for universals in medical research - that is, universals as abstracted from the

⁵⁷Rebecca Dresser, for example, cites a case of a researcher who asked investigators about the exclusion of Afro-Americans from clinical trials and received the response that they had never thought about the matter. See Dresser, fn 46 above at 28.

⁵⁸See, for example, Taylor, C *Sources of the Self* (1989).

⁵⁹See Habermas, J *Justification and Application* (1992) at 12.

⁶⁰Categories used by Gronewold, H 'Science and Macroethics on a Finite Earth' cited in Apel, fn 23 above at 227.

⁶¹Apel, fn 23 above at 228.

plurality of experience.⁶² Kant, however, is an inadequate authority without modification. The purpose of the next section is to outline Kant's theory⁶³ and to show how Habermas has transformed it.

4.2.6. KANT

4.2.6.1. The Categorical Imperative (CI)

The categorical imperative as set out in *The Groundwork of the Metaphysic of Morals*⁶⁴ consists of the formula of universal law which provides that one should act only on a maxim which one believes should be a universal law.⁶⁵ In other words, *do not unto others which you would not do to yourself*. The formula of the end-in-itself provides that one should act in such a way that humanity is treated as a means and not as a means to an end.⁶⁶ Lastly, the formula of the kingdom of ends provides rational beings with a share in the making of universal law.⁶⁷

It is arguable that the maxim of the end-in-itself renders the conduct of research involving human subjects impossible if one accepts the basic tenets of Kantian philosophy.⁶⁸ Kant, however, cannot be dismissed so lightly;

“...there is nothing of itself objectionable in using others as a means to our ends. We do this all the time quite ethically and legitimately. The blood transfusion service is a good example. All blood donors are used by recipients as means to their ends. The ethic that requires us not to use people as means is derived from the Kantian principle that we should treat people not merely as means but always as ends in themselves. I am not sure precisely what this means but I suppose that it is that we should not in our relations with others deny their personhood.”⁶⁹

⁶²O'Neill, fn 36 above at 126-144 and also Körner, S *Kant* (1955) at Chapter Six.

⁶³See the *Groundwork of the Metaphysic of Morals* (23rd edn, 1989 Paton, H J (tr)).

⁶⁴Kant, fn 63 above. Hereinafter cited as G, IV, etc.

⁶⁵Kant, fn 63 above at G, IV, 421.

⁶⁶Kant, fn 63 above at G, IV, 429.

⁶⁷Kant, fn 63 above at G, IV, 434, G, IV, 433 and G, IV, 436.

⁶⁸Wulff, H R 'The ethics of animal and human experimentation' (1995) 346 *Lancet*.

⁶⁹Harris, J *Wonderwoman and Superman* (1992) at 123.

However, one interpretation of the CI is that it provides a basis for the conduct of research if we presume that it demands that we *strive* to adopt morally worthy maxims.⁷⁰ Thus, for example, the maxim that research subjects must not be used as a means to an end is not an absolute but rather that researchers should strive not to use research subjects as a means to an end as much as it is possible. This interpretation relies on the definition of a maxim as being a rule which is more or less consistent with the way you live your life.⁷¹ Thus, maxims delineate subjective practical principles - in other words, they allow principles to be modified by circumstances at any given time. This position allows for a degree of flexibility; maxims are not unchangeable dispositions.⁷² Researchers can therefore use research subjects the limit being set by unacceptable impairment of the subjects' autonomy. In short, Kant does not say that we should not treat people as means in any respect but that people should not be treated *merely* as means to an end.

A further criticism of Kantian philosophy is that it is too formalist⁷³ and the product of abstract universalism; it is consequently insensitive to context. The CI is regarded as being ruled by the terrorism of pure conviction whereby even immoral deeds can be sanctioned if they satisfy higher ends.⁷⁴

Kantian philosophy has also been questioned as being an appropriate basis for rights.⁷⁵ Campbell, for instance, argues that Kant places too much emphasis on the concept of autonomy and that his theory is both too individualistic and absolutist. This is a major disquiet, which has been taken up by contemporary feminist theorists who stress the importance of assessing moral questions within the social dimension.⁷⁶ Campbell proposes an alternative model for patients' rights by arguing that dependency, or need, is

⁷⁰O'Neill, fn 36 above at 131.

⁷¹See Habermas, fn 59 above at 6-7.

⁷²O'Neill, fn 36 above at 129.

⁷³Gillon, fn 14 above at 17.

⁷⁴See Habermas, fn 2 above at 196-197.

⁷⁵Campbell, A V 'Dependency: the foundational value in medical ethics' in Fulford, K V M and Gillett, G J M (eds) *Medicine and Moral Reasoning* (1994) at 189.

⁷⁶See for example, Gilligan, C *A Different Voice* (1982), Brown, fn 45 above at 165 et seq and also McHale, J, Fox, M and Murphy, J, fn 45 above.

an integral facet of our autonomy. In effect, we can only realise our autonomy within the framework provided by society, a concept which is rooted in Aristotelian and Hegelian philosophy.

Be that as it may, the legitimacy of using human beings in medical research addresses the ultimate dilemma of balancing the interests of the patient as against those of society, an issue which is of the utmost importance, not least because, as liberalists would hold, the differing interests are irreconcilable. Applying Campbell's position, research could be justified with an appeal to society, namely, that there is a duty to engage in research in the sense of an obligation towards the community. Communitarians would support this position in the sense that their world is framed by a social compact which acknowledges the relationship to our fellow man, stretching between and beyond generations.⁷⁷

The categorical imperative is **not** a moral code or a moral algorithm; it can, however, demand morality as well as legality. As regards the medical research process, it is better suited as a procedural step by which principles for medical research can be ascertained on a continuing basis. Thus, it can be used to enable all those affected to take part in the medical research debate.

The use of Kantian philosophy as a basis for the moral reasoning underlying medical research can be defended on four counts. First, the provision concerning universality - or the formula of universal law - lies at the heart of the categorical imperative. In effect, this supports the notion that all interests must be afforded recognition. Secondly, the formula of the end in itself upholds the recognition of personhood. Thirdly, the formula of the kingdom of ends provides that everyone's will must be recognised; this qualifies them as being part of the kingdom of ends. Hence, there is no exclusion. There is no black will, no female will but only human will. Lastly, Kant is firmly anti-élitist to the extent that he explicitly states that no privileges accrue to philosophers;

⁷⁷See Elshthain, J B 'The Communitarian Individual' in fn 4 above at 99.

“On the practical side, however, the power of judgement first begins to show what advantages it has in itself when the ordinary mind excludes all sensuous motives from its practical laws. Then ordinary intelligence becomes even subtle-it may be in juggling with conscience or with other claims as to what is most important, it can in the latter case have as good hope of hitting the mark as any that a philosopher can promise himself. Indeed it is almost surer in this than even a philosopher, because he can have no principle different from that of ordinary intelligence, but may easily confuse his judgement with a mass of alien and irrelevant considerations and cause it to swerve from the straight path. Might it not then be more advisable in moral questions to abide by the judgement or ordinary reason and, at the most, to bring in philosophy only in order to set forth the system of morals more fully and intelligibly and to present its rules in a form more convenient for use (though still more so for disputation)-but not in order to lead ordinary human intelligence away from its happy simplicity in respect of action and to set it by means of philosophy on a new path of enquiry and instruction ?”⁷⁸

A case of too much abstract thought leading to intellectual vertigo ? Kant was not being elitist; he refers to the categorical imperative as an exercise in **practical reason**. Not everything can be grasped by the sciences. One is reminded of Mary Wollstonecraft,

“...I must add that I do not believe that a private education can work wonders which some sanguine writers have attributed to it. Men and women must be educated, in a great degree, by the opinions and manners of the society they live in. every age there has been a stream of popular opinion that has carried all before it, and given a family character, as it were, to the century. It may then fairly be inferred, that, till society be differently constituted, much cannot be expected from education. It is, however, sufficient for my present purpose to assert that, whatever effect circumstances have on the abilities, every being may become virtuous by the exercise of its own reason.”⁷⁹

Or as William Hazlitt summarises eloquently out it in his essay, *‘The Ignorance of the Learned’*;

“Learning is, in too many cases, but a foil to common sense; a substitute for true knowledge. Books are less often made use of as ‘spectacles’ to look at nature with, than as blinds to keep out its strong light and shifting scenery from weak eyes and indolent dispositions. The book-worm wraps himself up in his web of verbal generalities and sees only the glimmering shadows of things reflected from the minds of others.”

And further,

⁷⁸Kant, fn 63 above at G, IV, 404.

⁷⁹*A Vindication of the Rights of Woman* (1992) at 102-103.

"He clings to it [his book] for his intellectual support; and his dread of being left to himself is like the horror of a vacuum. He can only breathe a learned atmosphere, as other men breathe common air. He is a borrower of sense. He has no ideas of his own, and must live on those of other people."⁸⁰

This is an issue which has been taken up more recently by Isaiah Berlin;

"For, as Tolstoy taught us long ago, the particles are too minute, too heterogeneous, succeed each other too rapidly, occur in combinations of too great a complexity, are too much part and parcel of what we are and do, to be capable of submitting to the required degree of abstraction, that minimum of generalization and formalization-idealization-which any science must exact."⁸¹

In essence, Berlin argues that practical wisdom or reason is the ability to synthesise the "...fleeting, broken, infinitely various wisps and fragments that make up life at any level, just as every human being, to some extent, must integrate them (if he is to survive at all), without stopping to analyse how he does what he does, and whether there is a theoretical justification for his activity."⁸² Hence,

"Sciences, theories no doubt do sometimes help, but they cannot be even a partial substitute for a perceptual gift, for a capacity for taking in the total pattern of a human situation."⁸³

The central point is that there is an over reliance on theory in the sciences.⁸⁴ This leads to, among other things, trying to alter facts to fit a theory. Thinking by analogy is limited in view of its foundation in induction; it cannot take into account the variety and variability of human experience. Each particular situation is constituted by a unique combination of characteristics.

⁸⁰Hazlitt, W *Table-Talk. Essays on Men and Manners* (1901) at pp. 92-93.

⁸¹Isaiah Berlin 'On Political Judgment' (1996) XLIII *The New York Review of Books* 27 at 29.

⁸²Berlin, fn 81 above at 28.

⁸³Berlin, fn 81 above at 29.

⁸⁴"Utopianism, lack of realism, bad judgment here consist not in failing to apply methods of natural science, but on the contrary, in over applying them. Here failure comes from resisting that which works best in each field, from ignoring or opposing it either in favor of some systematic method or principle claiming universal validity - say the methods of natural science (as Comte did), or of historical theology or social development (as Marx did) - or else from a wish to defy all principles, all methods as such, from simply advocating trust in a lucky star or personal inspiration: that is, mere irrationalism". Berlin, fn 81 above at 29.

Berlin's position can be summarised thus: human experience as well as 'pure' logic must be valued notwithstanding the fact that the boundaries are not as clear cut as it is often assumed. How then can the method of analysis be sensitive to the plurality of experience and not to the restricted experiences of the professional élite ? How can the professional élite be sensitive to the general public ? How can the public operate within the medical research process ? In short: how can we enable all those affected to take part in the medical research debate ? The categorical imperative takes us some way towards doing this but not far enough. To lead us the rest of the way we need to look to Jürgen Habermas who has developed his social theory of debate ethics by placing Kantian ethics on a pragmatic footing.

4.2.7. HABERMAS AND DEBATE ETHICS

The importance of debate ethics is its stress on intersubjectivity; it does not use the atomistic, individual reflective subject, as Kant did, as its line of departure. In essence, it recognises that how one should live is not just an individual problem. We must not be egocentric but must look to the needs of others.

Debate ethics replaces the Kantian CI with a procedure of moral argumentation.⁸⁵ It provides that a norm is correct and valid if it is the result of a certain procedure of discussion and it meets with the consent of all affected.

Thus,

1. Everyone who can speak may take part in debate.
2.
 - (a) Everyone may question any assertion.
 - (b) Everyone may introduce any assertion into the debate.
 - (c) Everyone may express his or her attitudes, wishes, and needs.
3. No speaker may be prevented from exercising the rights laid down in (1) and (2) by any kind of coercion internal or external to the debate.⁸⁶

⁸⁵Habermas, fn 2 above at 197. See also generally Habermas, fn 59 above at 43-115 and also Apel K-O, fn 23 above at 136 et seq. Alexy, R 'Debate Theory and Human Rights' (1996) 9 Ratio Juris 211.

Debate ethics necessarily entails freedom and equality of argument; it rests on the 'ideal speech situation' which incorporates the notion of consensus under ideal conditions of discourse. For example, a reason given for an assertion must be a good reason for everyone and a person making an assertion must be able to defend it against anyone. Habermas recognises that people have opinions on everything. One only has to take a look at forum television or listen to radio phone-ins to know that the concept that the public are passive in relation to issues of importance is based on a sweeping and erroneous generalisation. This is especially relevant concerning questions raised by medical ethics. For example, the controversy sparked by the case of Mandy Allwood in Britain which concerned whether it was morally acceptable for her to impose a financial liability on the National Health Service for what was a futile attempt to carry octuplets, seized the national consciousness; much of the debate was carried out in the press, tabloids and broadsheets alike. The case was covered in medical journals such as *The Lancet*⁸⁷ and the *British Medical Journal*⁸⁸ as well as the popular press such as the *Daily Telegraph* which referred to the case in the emotive terms 'The Death of Babies'.⁸⁹

Another example, is the case of Diane Blood,⁹⁰ whom the Human Fertilisation and Embryology Authority had banned from using the sperm taken from her husband when he lay dying in a coma because he had not given written consent; what is noticeable is that issues of medical ethics are becoming a matter of public consciousness and conscience with the media playing a central role. This kind of inclusion is the basis of legitimacy for democracy. The need to argue is part and parcel of human nature.

Habermas argues that the employment of reason must be three-fold. First, it must be pragmatic where the agent takes his own goals as a line of departure. He then applies it

⁸⁶Alexy, R *A Theory of Legal Argumentation* (1989 Adler, R and MacCormick, N (tr)) at 193. To enter into the debate, an assertion must be made; this is referred to as a speech act which raises a claim to truth / correctness to which there is an obligation to provide a justification.

⁸⁷See Dean, M 'British octuplet pregnancy upsets the medical applecart' (1996) 348 *Lancet* 605.

⁸⁸Dyer, C 'Selective Abortions in the Headlines' (1996) 313 *BMJ* 380.

⁸⁹*The Daily Telegraph* October 4, 1996 at p. 25.

⁹⁰*R v. Human Fertilisation and Embryology Authority, ex p Blood* (1996) 35 *BMLR* 1.

to possible contexts of application thereby achieving a reflective distance from his own life. This enables him to become an impartial critic and to ascertain generalizable knowledge to shared experience.⁹¹

Secondly, it must be ethical to the extent that it is good for you, all things considered. This decision is reached by using the 'I', the context of your experience from which you can not distance yourself as a line of departure. This is in tune with the person you are and the person you would like to be; thus your identity is responsive and at the mercy of self-understanding.⁹²

Thirdly, it must be moral to the extent that the answer to the question 'What should I do?' must not conflict with the interests of others. The agent must be able to will the result of his reasoning to be a general law?⁹³ This approach enables the incorporation of a higher level of intersubjectivity and intermeshed perspectives.⁹⁴ Habermas' theory is not anti-individualistic despite appearances to the contrary. It is, however, based on a rejection of neo-aristotelianism.⁹⁵ In his opinion, both Aristotle and Hegel subordinate the individual to an encompassing communal life; in effect, the individual is a hostage to the custom and traditions of society. This is, however, too vague and transcendental. A moral order which is linked to communal goals is not viable in the society we live in. First, where are the benchmarks which illustrate what these goals are? Secondly, it does not tell us how we are to get a consensus or how to co-ordinate social action. We can no longer count on a shared ethos. We cannot, using widely adopted terminology, agree on the definition of the good to the extent that it refers to personal preferences of ways of life. We can, however, agree on the definition of the right to the extent that it refers to general procedures in which plans for our lives unfold.

⁹¹Habermas, fn 59 above at 11.

⁹²Habermas, fn 59 above at 12.

⁹³Habermas, fn 59 above at 7.

⁹⁴Akin to Carol Gilligan's connection thesis. See Gilligan, fn 76 above.

⁹⁵For a definition of neoaristotelianism see Schnädelbach, H 'What is Neoaristotelianism?' (1987/88) 7 Praxis International at 225.

Debate ethics is a break with the egocentric character. Thus,

“Pragmatic debates point to the necessity of compromise as soon as one’s own interests have to be brought into harmony with those of others. Ethical-political debates have as their goal the clarification of a collective identity that must leave room for the pursuit of diverse individual life projects.”⁹⁶

The outcome of this position is that norms for medical research are universal. Secondly, the moral reasoning for the debate centres on application. Application needs a new discursive procedure governed by the principle of appropriateness (*Angemessenheit*).⁹⁷

The reason why this approach is concretely better for the medical research debate is that it allows for the inclusion of different view points which include, *inter alia*, the views of women and the black community. Moreover, as both Kant and Berlin testify no-one has a privilege in deciding the norms for medical research; there is no ‘higher’ viewpoint.

Debate ethics has, however, several drawbacks; it is by no means, a perfect solution. In particular, two problems with the ideal speech situation arise.⁹⁸ The first concerns the difficulty of attributing weight to opinions. This was an issue which was raised in the previous chapter. The second concerns the need for procedures for conflict resolution. One is reminded of the dialogue between Baum and Thornton, in which the latter was merely invited to air her views as opposed to stating her views as of right. Thus,

“Encouraged by myself and other clinical scientists she suddenly finds that she is invited to scientific meetings to express her views, is offered privileged space in such learned journals as the *Lancet* and has had the opportunity to sit down and discuss these issues with some of the finest brains in the business. This alone demonstrates the openness of the scientific process that welcomes dissenting voices, as without dissent there can be no progress.”⁹⁹

⁹⁷Habermas, fn 59 above at 16.

⁹⁷Cf Günther, K *Der Sinn für Angemessenheit* (1988) and also Günther, K ‘Impartial Application of Moral and Legal Norms: A Contribution to Debate Ethics’ in Rasmussen, D (ed) *Universalism vs. Communitarianism: Contemporary Debates in Ethics* (1990) at 199.

⁹⁸See Section 4.2.7. above.

⁹⁹Baum, M ‘Clinical Trials - A brave new partnership: a response to Mrs Thornton’ (1994) 20 J Med Eth at p. 23.

The difficulties of the ideal speech situation are illustrated by Dorothea's views of Mr Causaubon as a listener in *Middlemarch*. Thus,

"...she found in Mr Causaubon a listener who understood her at once, who could assure her of his own agreement with that view when duly tempered with wise conformity, and could mention historical examples before unknown to her."¹⁰⁰

Dorothea's view of herself is, by comparison, servile, to say the least. Moreover, it is apparent from a later exchange involving Sir James Chettam, who wishes to experiment with patterns of farming among his tenants, and whom Dorothea defends, just how little weight her views carried in the Middlemarch society, including Causaubon. The exchange between Chettam, Brooke and Dorothea is interesting for a further reason. Chettam wants to experiment with farming after having read a textbook on the subject,¹⁰¹ a move to which Mr Brooke dismisses as unwise;

"A great mistake, Chettam,' interposed Mr Brooke, 'going into electrifying your land and that kind of thing, and making a parlour of your cow-house. It won't do. I went into science a great deal myself at one time; but I saw it would not do. It leads to everything; you can't let nothing alone.'"¹⁰²

Dorothea defends him;

"'Surely,' said Dorothea, 'it is better to spend money in finding out how men can make the most of the land which supports them all, than in keeping dogs and horses only to gallop over it. It is not a sin to make yourself poor in performing experiments for the good of all.'"¹⁰³

To which Mr Brooke replies,

"'Young ladies don't understand political economy, you know,' said Mr Brooke, smiling towards Mr Causaubon.'"¹⁰⁴

¹⁰⁰"'He thinks with me,' said Dorothea to herself, 'or rather, he thinks a whole world of which my thought is but a poor two-penny mirror. And his feelings too, his whole experience - what a lake compared with my little pool !' Eliot, G *Middlemarch* Harvey, W J (ed) (1985) at p. 47.

¹⁰¹Davy, H *Elements of Agricultural Chemistry* (1814). See Note 1 in Eliot, fn 100 above at 898.

¹⁰²Eliot, fn 100 above at 39.

¹⁰³*Ibid.*

¹⁰⁴*Ibid.*

Despite the fact that Dorothea is included in the discussion, it is apparent that Mr Brooke does not take Dorothea seriously.¹⁰⁵

4.3. CONCLUSION

A debate theoretical approach demands that we need to go beyond theory as regards ethical speculations concerning questions of justice and thereby need to enter into a real process of argumentation under certain conditions and with a variety of agents. Thus, philosophers have a role in the medical research debate, they are experts who should take part in the planning and the decision-making of medical research.¹⁰⁶ Their role, however, must be qualified and this can best be achieved by adopting an approach based on debate ethics. This depends on institutionalising democratic procedures. Thus,

“...[t]he unity of practical reason can be realized in an unequivocal manner only within a network of public forms of communication and practices in which the conditions of rational collective will formation have taken on concrete institutional form.”¹⁰⁷

And further,

“From the perspective of a theory of debate, the problem of agreement among parties whose wills and interests clash is shifted to the plane of institutionalized procedures and communicative presuppositions of processes of argumentation and negotiation that must be actually carried out.”¹⁰⁸

The first problem with which we must concern ourselves is what these principles look like in their concrete form. Secondly, there are difficulties with the ideal speech situation in respect of the weight of opinion in the resolution of conflict. For this, we need to get

¹⁰⁵“It is not enough to extract universalistic principles from communicative structures and then assume that one can engage in a normative discourse free of power.” Delanty, G ‘Habermas and Occidental Rationalism: The Politics of Identity, Social Learning and the Cultural Limits of Moral Universalism’ (1997) 15 *Sociological Theory* at p. 56.

¹⁰⁶Habermas, fn 7 above at 351.

¹⁰⁷Habermas, fn 59 above at 17.

¹⁰⁸Habermas, fn 59 above at 16.

a clearer view of the medical research process and, to this extent, we need an interdisciplinary approach. As we shall see, these issues come into their own in the dynamics of research ethics committees; the purpose of the next section is to see to what extent, the practice of research ethics committees illustrate the deficiencies of the medical research debate. Two questions arise. To what extent, do they represent an outlook which is that of the professionalised élite ? And secondly, to what extent are these committees able to embody the principles of democratic institutionalisation ?

CHAPTER FIVE

RESEARCH ETHICS COMMITTEES IN THE UNITED KINGDOM

"The often equally aggressive and impotent resistance of lay people is replaced by the opportunities sciences have for resistance: counter - criticism, methodological critique, as well as a clubbish 'obstructive behavior' in all the fields of professional competition for resources."

Ulrich Beck¹

INTRODUCTION

The research ethics committee (REC) is central to the control of medical research involving human subjects. It provides a forum within which individuals can scrutinise proposals and decide on their validity. Public scrutiny lay at the heart of the stated aims of the 1991 guidelines issued by the Department of Health (DoH)² which were seen as forming part of the Citizen's Charter. Greater accountability of researchers towards the public as a whole rather than to the medical establishment alone was held to be paramount. At their launch in August 1991, the then UK Minister for Health, Virginia Bottomley said,

" Research is the lifeblood of medical science and the NHS is at the leading edge. These changes will further improve the public scrutiny of medical research."³

To what extent, however, is the public scrutiny referred to by Mrs Bottomley limited or even mythical ? The experience of research ethics committees in practice has provoked a number of criticisms. These include, first, the absence of a supervisory body entrusted

¹Beck, U *Risk Society; Towards a New Modernity* (Trans. Ritter M 1992) at p. 160.

²Local Research Ethics Committees, Department of Health (DoH) (1991) replacing HSC (15) 153 (1975).

³Reported in (1991) 17 J Med Eth at p. 217.

with monitoring the practices of committees; there is, as yet, no body which is responsible for auditing the work of the RECs although this role has been filled in the commercial sector by a number of consultancies.⁴ Secondly, information concerning RECs and their practices is not, as a rule, made readily available to the general public. For example, information concerning membership, frequency of meetings, the number of proposals dealt with each year, the nature of the proposals considered and objections raised are not thought to be a matter for public concern. Such information is, admittedly, contained in annual reports which most committees now publish.⁵ The standards of annual reports, however, vary greatly, as was discovered by Nicholson in his study of research ethics committees.⁶ Some of the reports which I obtained through field research conducted in Scotland in 1993-1994 were clearly inadequate and did not provide an overall picture of the committees' function and practices.⁷ There is, as yet, no official register of RECs in the United Kingdom and it has, again, been the commercial sector which has led the field.⁸ Thirdly, the practices of RECs vary greatly and are haphazard. They are also undemocratic. The introduction of the research ethics committee by the declaration of Helsinki in 1964 has the 'compelling cover of democracy'⁹ - but what lies behind this cover? Study of the medical research committees reveals that the professional élite are over-represented in their current constitution; even a majority of lay members are selected from the professions. This, in

⁴As in the case of *Til Occam*, for instance. See fn 8 below.

⁵The DoH guidelines provides that, "Each year the LREC should submit a report to the DHA [district health authority], and copies should be sent to all the NHS bodies which the LREC exists to advise, and to the CHC [community health council]. The names of committee members, the number of meetings held and a list of proposals considered (including whether they were approved, approved after amendment, rejected or withdrawn) should be included. This report should be available for public inspection." DoH, fn 2 above at para 2.16.

⁶See Nicholson, R 'What do they get up to? LREC annual reports' (1997) 129 Bull Med Eth 13.

⁷See Appendix E. Despite every effort made, only 12 Committees Responded Out of a Total of 21 as regards Composition and 7 Committees out of 21 as regards Practices. This small sample does nothing more than show a general tendency. References to RECs in practice will be made in relation to fieldresearch and to the study undertaken by Nicholson, fn 6 above.

⁸A database of research ethics committees has been maintained during the last two years by *Til Occam Limited* in conjunction with the Royal College of Physicians. Note that many drug companies often want a list of the membership of the LREC but more often than not, are denied access to such information. In the United States on the other hand, the guidelines in relation to Institutional Review Boards (IRB) are far more stricter and IRBs are audited by force of law; the idea of providing a list of the membership of the IRB was in response to the concerns of many drug companies that the researcher might be on the Board.

⁹Galbraith, J K *The Culture of Contentment* (1995) at 10.

effect, both reflects and reinforces existing social stratification.¹⁰ Pluralism is defined narrowly with the result that REC decisions are the product of a particular kind of “common sense”. Lay members of research ethics committees are not selected from a wide cross section of the community and, as a result, proposals for research are not assessed by a diversity of opinion; the input of the community is restricted. To this extent, the decisions of RECs can be seen as lacking the support of a wider majority.

The fundamental question with which we are faced is: does society want to entrust the scrutiny and control of research to experts ? If this is the case, then the *status quo* in respect of research ethics committees in the United Kingdom could be described as satisfactory and proposals for reform could be limited to a few perfunctory remarks. If, on the other hand, it is felt that those who are responsible for scrutinising and controlling medical research ought to be representative of society as a whole, then the position of RECs in the United Kingdom falls short of the ideal - and comprehensively so.

The medical research debate, as outlined in the preceding chapters, is flooded by the professions. The forum of the research ethics committee is pervaded by the knowledge derived from several disciplines - scientific, legal and moral and, to some extent, theological. None of these discourses is unitary; none of them is a complete master of empirical reality. They are fragmented and contradictory; they are also partial. The difficulty lies in distinguishing those competing insights and assessing their relative claims to truth. A method is needed by which differing claims to knowledge can be reconciled. It must be determined whether everybody is equally able or whether some are better than others in determining questions about value - this dilemma lies at the heart of this thesis.

The research ethics committee is a forum in which competing schools of thought meet head to head.¹¹ Indeed, questions involving medical research have been intellectualised to such an extent that the debate is, perforce, monopolised by the professions¹² each of

¹⁰Putnam, R D *The Comparative Study of Political Elites* (1976) at 3.

¹¹See Douglas, M *How Institutions Think* (1987).

¹²Beck, fn 1 above at 168.

which has its own method of reasoning, its own vocabulary,¹³ its own 'thought collective'.¹⁴ Essentially, the parameters within which the professions analyse are institutionally defined because each school of thought favours one form of proposition over and above all others.¹⁵ These institutionalised ways of thinking clash within the forum of the research ethics committee.

It is arguable that this clash is inescapable when professions are seeking normative principles by way of a debate in which the discussants are products of varied forms of professional conditioning. The influence of professional conditioning is considerable if not overwhelming. Indeed, the institutions from which the professionals come have been described as having encompassing tendencies.¹⁶ The training which medical researchers, lawyers and philosophers receive is the product of institutions, each of which shares common characteristics or a 'family of attributes'. Institutions are ingrained with a sense of common purpose usually articulated, for example, in company policy. Good team players are called for; by implication, dissent or resistance are seen as being adverse to the cooperative effort. More critically, however, is the surrendering of thought or mental effort to the organization. "[t]hose serving it", as J K Galbraith writes, "have a powerful commitment to established belief and thus to established action".¹⁷ Not only does this involve a degree of powerful conditioning¹⁸ but it arguably diminishes the role of

¹³See Chapter Two, Section 2.2.

¹⁴The social anthropologist Mary Douglas describes a professional collective as one which 'leads perception and trains it and produces a stock of knowledge'. See Douglas, fn 11 above at 12 et seq.

¹⁵One is reminded of Berlin's remark concerning philosophical schools of thought. Berlin, I *Concepts and Categories: Philosophical Essays* (1980) at 57. See Chapter Two, Section 2.2.

¹⁶I base my analysis on Erwin Goffman's book *Asylums; Essays on the Social Situation of Mental Patients and Other Inmates* (1961). His findings are not specific. What we learn about some institutions will teach us about others. "Every institution captures something of the time and interests of its members and provides something of a world for them; in brief, every institution has encompassing tendencies." See Goffman, at p.15.

¹⁷Galbraith, fn 9 above at 68.

¹⁸"The organization man is happy with what exists. As this mood controls his private life, so it controls his public attitude. Nothing so breeds acquiescence in, or indifference to, social shortcomings as daily exposure to the misjudgments, eccentricities and inanities of private organization." Galbraith, fn 9 above at 68.

thought itself. In the higher echelons of the organisation, thought is something which is delegated as opposed to being confronted.¹⁹

These ideologies or shared categories of thought which tie the individuals to the institution²⁰ have a common denominator. Scientists, lawyers and philosophers are taught to win over their opponents by force of argument; they are schooled according to adversarial precepts - they are not taught to mediate.

A further issue which distorts the concept of democratic control of research ethics committees is that of language. As was argued in Chapter Two, power is asserted through language. Very often, it is a case of the survival of the fittest - the party with the greater understanding is able to exercise disproportionate influence over the medical research debate.²¹ Those who control language, control rationality. The task with which lay members are faced is coming to terms with the language in which research proposals are discussed. Those who can understand what is involved can also participate in rational discussion.

Questions of ethics lead to conflicts; this calls for conflict resolution;

“Ethical debates are extremely unlikely to result in unanimity. Though rational discussion is possible, personal values and innate feelings will often prove resistant to change and may remain persistently polarised among members of a society. In this context there is a need to develop democratic systems of decision-making in order to resolve conflicts.”²²

¹⁹“Encountering a problem, an organization man turns naturally, automatically, to a subordinate. The latter is told to get on with it. This he then does by turning to an assistant, and the delegation continues. The culture of organization runs strongly to the shifting of problems to others-to an escape from personal mental effort and responsibility. This, in turn, becomes the larger public attitude. It is for others to do the worrying, take the action. In the world of the great organization, problems are not solved but passed on.” Galbraith, fn 9 above at 69.

²⁰Goffman, fn 16 above at 159.

²¹See Chapter Two, Section 2.4.3.

²²New, B on behalf of the Rationing Agenda Group ‘The rationing agenda in the NHS’ (1996) 312 BMJ 1593 at 1596-1597.

Two models for the regulation of medical research can be distinguished. The first is adversarial which, inevitably, entails a confrontation of institutionalised affiliations and ways of thinking. In a model based on mediation, however, there is room for everyone in the decision-making process. Thus, successful mediation evolved into a process of *collective mediation* and the inclusion of the general public in the debate is, thereby, rationalised.

The arguments underlying the next section can be summarised as follows. We need experts. We also, however, need lay members on research ethics committees who are selected from a wide section of the community. A comparison will be made with Childrens' Panels which operate in Scotland and whose members are representative of the communities which they serve. The implementation of parallel structures, such as Citizens' Juries for instance, will also be advocated so that representatives of public opinion may have the opportunity to participate in the decision-making process especially concerning the wider implications raised by medical research proposals. This calls for a refinement of the existing regulatory framework along pluralistic lines which can be achieved through procedural reform. The existing structure, including its shortcomings will be investigated in the light of this suggestion.

5.1. THE PRACTICES OF RESEARCH ETHICS COMMITTEES

5.1.1. REMIT AND COMPOSITION

The research ethics committee as a model of decision-making is an American export. Institutional Review Boards (IRB), as they are referred to there were established during the sixties as a way of introducing peer review for researchers. IRBs, however, must be distinguished from hospital ethics committees which are concerned with the ethical validity of methods of treatment. Even in the United Kingdom we must establish the level of which we are speaking. A research ethics committee can be formed, at its lowest

level within a ward or department but, commonly each hospital has its own committee which is responsible for the management. To rely upon such committees would, however, be to fragment control to an unreasonable extent and the establishment of research ethics committees at a local level (LRECs) is now common place. Throughout this thesis, unless it is stated to the contrary, this is the form of REC which is under discussion.

The Department of Health guidelines²³ and those provided by the Royal College of Physicians²⁴ provide, *inter alia*, that membership of research ethics committees should include both sexes as well as a range of age groups. Furthermore, hospital medical staff, nursing staff, general practitioners and at least two lay members must be represented.²⁵ The number of committee members should range from eight to twelve members.

5.2.1. EXPERTISE AND THE LAYPERSON

Committees depend on individuals with expertise; indeed, expertise is essential to the review process and in practice, RECs are dominated by the professional élite. This is, however, not without its problems.

The compulsory introduction of laypersons is intended as a counterbalance but the role of the lay members may be more symbolic than of practical value. Lay members must depend largely on experts in order to form an understanding of what a given proposal entails. The fundamental difficulty of the committee therefore lies not so much in the constitutional balance of experts and lay people but, rather, in the formers' expertise in imparting the necessary information to the latter.

²³See fn 2 above at paras 2.4. and 2.5.

²⁴Royal College of Physicians *Guidelines on the Practice of Ethics Committees in Medical Research involving Human Subjects* (3rd edn, 1996).

²⁵See Appendix E.

Medical researchers will, for example, understand what is meant by a risk of 5 % chance that incontinence will ensue as a result of an epidural anaesthetic administered during the course of a clinical research trial. The difficulty arises when they have to explain this risk to individuals who have not had the benefit of medical training. The problem is one of language;

“...every individual is bound by language. She internalizes the rules of the language games, especially in the native language. People develop (alter) the language but they cannot escape it. Everybody living in a certain linguistic community is a prisoner of the language. It is the basis for social behaviour.”²⁶

A difficulty of imparting knowledge gained through expertise to lay people will come within the ambit of what has been referred to as the ‘gap between persons’.²⁷ In essence, this gap is amplified where the expertise of the parties is unequal and this in turn gives rise to inequalities of language. It highlights the nature and the roles of the social relationships which exist in the medical research process. The party who commands language commands the situation.

The medical research process contains many language forms. Consider, for example, the language used in research proposals, that which is used during the deliberations of research ethics committees and that used in obtaining consent from research subjects. Consider also the language used in applying for funding and the language used in the submission of the results of research for publication. In each example, the use of language involves a ‘translation’ of ideas.

Any exercise in translation necessarily involves a degree of interpretation;

“Everybody who has done some translating, and who has thought about it, knows that there is no such thing as a grammatically correct and also almost literal translation of any interesting text. Every good translation is an *interpretation* of the original text; and I would even go so far as to say that

²⁶Aarno, A and Pecznik A, ‘On Values: Universal or Relative ?’ (1996) 9 Ratio Juris 321 at 323.

²⁷Laing, R D *The Politics of Experience* (1967) at p. 42.

every good translation of a nontrivial text must be a theoretical reconstruction.
Thus it will even incorporate bits of a commentary. “²⁸

Essentially, Popper places more emphasis on understanding and interpretation than simplistic linguistic perception. Understanding can, however, be ‘doctored’. Language can not only shape the way in which we see the world but it can also distort our view. Understanding the socio-political dynamics of the medical research process entails understanding how it is discussed. This helps us to ‘flag’ both interests and hidden agendas. For example, members with expertise may have a certain bias towards promoting research by virtue of their training instead of having regard to the well-being of research subjects and the community. Moreover, experts may have an interest in the outcome of the research insofar as a significant result would most certainly bolster the reputation of the institution concerned.

Thus, one can say that, on the one hand, experts are needed to lay the foundations of the decision-making process. On the other hand, however, their role, needs to be defined so that the possibility of their expertise being used as a manipulative instrument is limited. The purpose of this next section is to consider how this problem affects the individual members of research ethics committees.

5.2.1.1. THE ROLE OF MEDICAL PROFESSIONALS

The presence of the medical profession on RECs is justified because of their expertise which enables them to understand the substance of research proposals. Even though the precise nature of the project may be beyond their own specialist knowledge, they will be able to appreciate its concept by way of professional instinct by virtue of their extensive training. These concepts must, however, be reduced to plain language. A common criticism which is often levied at ethics committees is that lay members do not always comprehend the medical issues at stake because the proposals are framed in scientific terms and concepts which are often complex; this may have the effect of inhibiting and to

²⁸Popper, K. *Unended Quest : An Intellectual Autobiography* (1976) at 23.

some extent limiting the input of lay members in the decision-making process. Given these difficulties, it is arguable that a medical professional member should be selected who is entrusted to 'translate' research proposals for the lay members and any other interested groups, such as Citizens' Juries.²⁹

The DoH guidelines provide that where a committee is faced with a proposal which it is not able to assess sufficiently, it may rely on the advice of specialist referees.³⁰ A committee may invoke this provision if it is of the opinion that a proposal is outside its ambit of expertise. The guidelines do not, however, contain specific provisions for the possibility of having an active member of the REC who would be responsible for 'translating' proposals into everyday language so that lay members as well as the eventual patients or volunteers are able to understand the nature of the research involved.

The provision of a medical referee is by no means standard practice. Nicholson found that only one teaching hospital LREC employed a doctor on a sessional basis to clarify proposals for lay members.³¹ The membership of the Tayside Committee on Medical Ethics in Scotland includes a medical adviser who is responsible for helping lay members to reach opinions based on a solid understanding of the scientific material before them. The committee's constitution states that,

"In addition it was agreed that the adviser on medical matters to the Chairman and other lay members should scrutinise each protocol in detail and report his views in writing to them."³²

The role of the medical adviser is to explain the medical terminology. Moreover, he has to interpret the information, form an understanding of the aims of proposal and pass on

²⁹Citizens' Juries are discussed below at Section 5.6.3. Of course a translator would be unnecessary in an ideal world.

³⁰See fn 2 above at para 2.10: "LREC members should, on its own initiative seek the advice of specialist referees or co-opt members to the committee so as to cover any aspect, professional, scientific, or ethical of a research proposal which lies beyond the expertise of existing members."

³¹Nicholson, fn 6 above at 24.

³²Tayside Committee on Medical Ethics *Annual Report* (October 1990 to 30th September 1991) at p. 4.

this understanding to the lay members. Practice may, however, fall short of the ideal if, as Popper maintains, every translation is an interpretation.³³ Not only does a medical adviser's translation rely on his interpretation, but a lot also depends on how his interpretation is perceived by lay members. One possibility is that their perception may be based on blind trust. Consider Dorothea's predicament in George Eliot's novel, *Middlemarch*;

"Dorothea's faith supplied all that Mr Casaubon's words seemed to leave unsaid: what believer sees a disturbing omission or infelicity? The text, whether of prophet or of poet expands for whatever we can put into it, and even his bad grammar is sublime."³⁴

Thus, the possibility of bias in the use of language by a medical adviser or those members of a REC who undertake to translate research proposals is a real consideration. The dividing line between explaining a case and assessing it may be blurred. A medical adviser who extends his role to giving an opinion on the merits of a proposal must surely be guilty of an unacceptable bias. Thus, even though a medical adviser is an invaluable asset to committees his role must be limited to the explanation of facts and must not extend to an evaluation or opinion concerning the ethics of the proposal. The same can be argued in relation to other members of the committee. Let us turn our attention to the legal profession.

5.2.1.2. LAWYERS

The current trend indicates that lawyers are a popular choice as regards the selection of lay members for RECs.³⁵ In theory, such people are appointed only in the capacity of a lay person but, inevitably, they will be used to comment on the legal implications of any project. There can be no doubt that legal advice regarding research proposals is invaluable, particularly as to questions of liability. The case of Mrs Margaret Wigley in

³³Popper, fn 28 above at 23.

³⁴Harvey, W J (ed) (1985) at 74.

³⁵Fieldresearch revealed that lawyers make up 23% of the lay membership of RECs in Scotland. See Chart 2 in Appendix E.

1981 is instructive.³⁶ This woman was entered into a drug trial without her knowledge and died as a direct result. The clinical trial in which she was involuntarily enrolled had received the approval of no less than eleven research ethics committees which leads one to question whether RECs and their members ought to be held accountable for their decisions.³⁷ By having legal representation, RECs would be able to assess research proposals taking the legal consequences their decisions may have into account.

What, then of the legal members of the REC ? If they are there as lay people, their role is no more than to comment on the acceptability of a research project to a non-medical person. Most people would, however, regard this as a waste of expertise - given that you have a lawyer on your committee, should not he or she be used to assess the legal consequences of any decision taken ? But, almost before we realise it, we are then confusing fact with opinion in the same way as we observed in the context of the medical representatives. Moreover, the committee is, effectively, obtaining a free legal opinion while, at the same time, anticipating that a duty of care is owed by the legal member of the committee to the committee as a whole. This is clearly unjust. A committee decision must be the responsibility of the whole committee. The logical conclusion is that any legally qualified member of the committee must be there as a lay, non-professional person.

The difference between the medical member and the legal member of the committee who is acting in a professional capacity is that the former is concerned with 'what is' while the latter is looking to 'what might be'. In short, the medical professional is concerned only with fact while the lawyer's input is bound to be a matter of opinion or conjecture. There may well be a case for the REC employing a legal adviser. But to recruit that adviser from its own ranks is unwise and, probably, unethical.

³⁶Editorial comment 'Secret Randomised Clinical Trials' (1982) 2 *Lancet* 78.

³⁷See McHale, J 'Guidelines for medical research' (1993) 1 *Med L Rev* 180.

5.1.1.3. RELIGIOUS ADVISERS

Theologians are also popular choices as lay members of research ethics committees.³⁸ How representative are they of the society in which they live? The role of religion has been greatly eroded in Western societies and it is questionable whether the presence of theologians on RECs would reflect the interests of more than a large minority of society. It might be argued that religious representation would not be necessary and might be even counterproductive in that a Minister of religion may maintain a view which is based on principles that are foreign to researchers and research subjects alike. It could well be argued that organised religion and organised science are incompatibles, the former representing mere ideology and the latter the path to truth. This, however, sees the religious adviser as a protagonist of a particular doctrine and, since many of us do not know whether theistic religion itself, let alone which form of theism, is right, such a role must be seen as unacceptable within the framework of the research ethics committee.

One might, however, seek to advance the following position. It is self-evident that a qualified minister of religion has been instructed in moral philosophy irrespective of his or her denomination. We could, therefore, expect any minister to be able to give a competent view as to what is right or wrong. We have said that the lawyer is concerned with 'what might be'; we can say, equally, that the religious adviser is concerned with 'what ought to be'. The question then arises as to whether this is a matter of fact or of opinion - and the answer is 'a bit of each'. The minister thus takes on part of the mantle of both doctor and lawyer but his input to the discussion differs from that of the others in a fundamental way- that is, that his contribution carries with it no connotation of practical responsibility. Thus, it would not be 'unfair' in asking ministers to ventilate their expertise freely and, so long as this is confined to moral principles alone, it is arguable that they should be encouraged to do so as professional rather than lay members.

³⁸Fieldresearch revealed that the clergy make up 12% of the lay membership of RECs in Scotland. See Chart 2 in Appendix E.

This position must, however, be rejected in view of the central argument advanced in this thesis. Whilst the participation of religious members in the decision-making process is an invaluable asset to RECs, they should not provide the committees with definitive answers as to the ethical validity of research proposals. They could, however, inform the committee regarding the extent to which proposals may affect religious sensibilities.

Whichever attitude is adopted, there is a case for co-opting ministers of religion in much the same way as has been discussed under the heading 'lawyers'. An experiment which involved cutting hair of research subjects might be regarded as acceptable by Christians or Hindus but would, one imagines, cause considerable difficulties for subjects who were practising Sikhs. On a wider scale, the whole problem of xenotransplantation as presently conceived must involve some conflict with orthodox Judaism. Were such examples to arise, it would clearly be proper as well as the negative side. We have seen already that, say, women and the black community may resent being excluded from research. The same might well be true of diverse religious groups. RECs concerned with ethnically dominated areas would do well to take advice as to the likely response to the 'white male' research subject model to which reference has been made above.

Even so, ministers of religion cannot and should not be denied membership of RECs. Who, then, should be chosen? In the absence of some obvious indication as suggested above, the answer to the question depends, largely, on what is the national policy. In particular, it depends on whether the national policy exemplifies a melting pot philosophy of integration, which appears to be the case in the United Kingdom, or whether the policy is outlined in terms of attempting to accord ethnic traditions with specific recognition,³⁹ an example of which would be Australia.

It would clearly not be feasible for a variety of faiths to be represented as a routine. The simple answer is to decide on which is the largest religious constituency in the area and to have a religious member representing that constituency. Other members could be co-opted for specific purposes if the study involved specific religious beliefs. The

³⁹See Habermas, J 'Multiculturalism and the Liberal State (1995) 47 Stan L Rev 849.

Department of Health guidelines allow for this to the extent that they provide that RECs may obtain the advice of specialist referees or co-opt members to the committee in order to gain advice on professional, scientific or ethical matters which it feels is beyond their expertise.⁴⁰ The guidelines published by the Royal College of Physicians are similar in nature but are more detailed;

“In areas of particular difficulty or sensitivity, eg. research involving the fetus, neonates, breast cancer, pregnancy, ethnic minorities, it is useful to co-opt additional lay or professional advisers for an individual application or meeting.”⁴¹

Thus, there can be no doubt as to the REC’s power to co-opt as it finds necessary.

5.1.1.4. MEDICAL ETHICISTS⁴²

The number of philosophers who sit on research ethics committees is high.⁴³ The justification appears to be based in the notion that it is their role to consider the ethical implications of research proposals. The danger lies in the real possibility that the presence of such members might, in effect, confine ethical assessments to those who claim a grounding in moral philosophy. The same argument which was advanced in Chapter Four in relation to the role of moral philosophers in the medical research debate is posited here. Moral philosophers can facilitate discussions but they are not there to provide answers.⁴⁴

⁴⁰See fn 2 above.

⁴¹Royal College of Physicians, fn 24 above at 8.

⁴²By ‘medical ethicist’, I am referring to an individual who specialises in medical ethics as a branch of philosophy. American commentators would refer to such an individual as a bioethicist.

⁴³Fieldresearch revealed that medical ethicists make up 15% of the lay membership of RECs in Scotland. See Chart 2 in Appendix E.

⁴⁴Habermas, *J Moral Consciousness and Communicative Action* (1990 Lenhardt, C and Nicholson, S W (tr)) at 211 and McCall Smith, R A ‘Committee Ethics ? Clinical Ethics Committees and their Introduction in the United Kingdom’(1990) 17 J Law & Soc 124.

5.1.1.5. LAY REPRESENTATION

The Department of Health Circular does not define 'lay representation' nor does it specify how lay members should be chosen. The lay members who are recruited do not, in general, represent a cross-section of the community; as likely as not they are self proposed and self selected. How real is the concern that RECs like other minor 'Quangos' are plagued by 'professional committee people' ?⁴⁵

The criteria for the selection of lay members are linked to a professional benchmark. The Federal Regulations for Institutional Review Boards in the United States, for example, define 'non-scientific' in professional terms.⁴⁶ It has been said in relation to the composition of research ethics committees that,

"...despite the fact that we would all doubtless like to see ourselves as persons of "sound judgement" some individuals, because of their background, merely continue to serve the role which they do professionally."⁴⁷

Most members of RECs are chosen from a section of the community which is quite specific, one which is derived from the educated bourgeoisie, most of whom have been to university or have received higher education. A hidden assumption exists that this is the correct constituency because the decision-making process within a REC requires a certain level of understanding of science with which they have to come to grips in order to assess the acceptability of research proposals. The implication here is in favour of a particular kind of common sense.

⁴⁵A term used by Brian Sewell, among others; "...and the committee men and women who can point to inches in Who's Who listing their much boasted service to the public [?]" in 'The peer pressure that works for Britain' *The Evening Standard* March 4, 1997 at p. 11.

⁴⁶45 Code of Federal Regulations Part 46: Protection of Human Subjects (Revised as of October 1, 1989) as reproduced in Dael, van den W and Müller-Salomon, H *Die Kontrolle der Forschung am Menschen durch Ethikkommissionen* (1990) at 140. See § 46. 107 IRB Membership (c) Each IRB shall include at least one member whose primary concerns are in nonscientific areas; for example: lawyers, ethicists, members of the clergy. This definition involves an unreasonably limited concept of what is science.

⁴⁷Lecture given by Professor S A M McLean at the Scottish Office on April 29, 1994, 'Research and Training - An Overview'.

Factors in their social backgrounds conspire in placing non-professionals in a position of cultural inequality that is marked by a lack of *educational* attainment. Bisserset Moreau cites model answers to the question, 'What do those who fail lack *culturally* ?', which she poses in her article, 'Education, Ideology, and Class / Sex Identity';⁴⁸

"A way of expressing themselves," "a critical mind," "openness of mind" "a taste for nonutilitarian culture," "a theoretical mind," "a conceptual mind," "certain values"... "[they] don't feel the need to intellectualize problems."⁴⁹

The presence of lay members on RECs is necessary and can be invaluable in raising issues which exemplify lay concerns - including their own concerns, those of the eventual patients or volunteers and those of the community as a whole. Lay members should, however, be selected from a wide cross section of the community. They are, afterall, there to appreciate what is commonly referred to as the 'Yuck factor' - that is, objections to research proposals which arise from no more than the common man's intuition.⁵⁰ The corollary is that the working methods of the REC should be framed so as to enable them to contribute their experience, or as Sheila McLean has put it, to 'reinforce their layness'.⁵¹ McLean was in fact speaking of Scottish Childrens Panels which provide a persuasive example of the contribution that can be made by lay members who have been selected from a wider cross-section of the community to making communal decisions. This analogy is considered further below.

To summarise: the problems inherent in the use of the expert culture should be addressed in the light of the following recommendations. First, the role of the medical profession is there to inform the other members as to the scientific nature of research proposals. Lawyers should be there as laypeople who should not be prohibited from expressing their expertise when it is appropriate to do so. However, lawyers who are asked to comment specifically on the lawfulness or otherwise of a proposed method should be co-opted for

⁴⁸See Bisserset Moreau N, 'Education, Ideology, and Class / Sex Identity' in Kramarae, C, Schulz, O'Barr, W M (eds) *Language and Power* (1984) at 43-61.

⁴⁹Bisserset Moreau, fn 48 above at 51.

⁵⁰To put it in a different way, specialist problems are for the specialists which is a further reason why lawyers should not be on a REC as a laymember but should be there as of right.

⁵¹McLean, fn 47 above.

that purpose. It is unreasonable to impose legal responsibility for decisions of the committee as a whole on one or two members who are there to supply only a general overview. Thirdly, whereas philosophers may facilitate the discussions, their role is not to provide answers as to the ethics of proposals. Fourthly, including religious advisers as committee members should be optional, depending on the constitution of the local society; however, it is suggested, though for different reasons, that they, too, might be co-opted instead of being included as of right. Lastly, lay members should be selected from a wide section of the community.⁵² It may be advisable to include representatives of research subjects in some cases. What procedures are needed to implement these proposals? To address this question, we must now turn our attention to the problems that research ethics committees face in the decision-making process as a whole.

5.2. THE DECISION-MAKING PROCESS

The language used in the DoH 1991 guidelines emphasise very much the concept of pluralism. However, it regards pluralism in its loosest sense - in the sense of a breadth of opinion as opposed to multi-culturalism. A good example of this is to be found in the recommendation that each REC should include nurses as a routine in their professional capacity;⁵³ nurses have traditionally been invisible as regards the decision-making process and the recommendation is to be welcomed as an indication of their increasing importance in the provision of health care. The involvement of nurses in life and death decisions have also been formally been recognised in the courts.⁵⁴

⁵²It may be advisable to include representatives of research subjects in some cases. See McNeil, P *The Ethics and Politics of Human Experimentation* (1993) at p. 241 and also Nicholson, fn 6 above at 24: "An LREC invited a patient to address it about a trial that was worrying her and found it a very useful experience."

⁵³DoH, fn 2 above at para 2.5.

⁵⁴*Re C (a minor)* (1989) 2 All ER 782, per Lord Donaldson MR. "The problem of how to treat the terminally ill is as old as life itself. Doctors and nurses have to confront it frequently, but it is never easy."

Accommodating a breadth of opinion depends on structuring the forum in a way which enables all opinions to be taken into account; this should be based on an equal standing within the forum. But this, in turn, depends on one's interpretation of equality - whether it is equality of opportunity to participate or equality of influence. Adherence to the latter definition might lead to a situation in which decision-making within a REC came to a stand still. The same argument was raised in chapter four dealing with moral reasoning in the medical research debate; attention was drawn, in particular, to Project 2000 and the difficulties which have been experienced in practice since its implementation. Paradoxically, the same dangers might be foreseen as regards lay members of committees. The past 20 years have seen a backlash against the 'doctor knows best' tradition, a result of which has been that the medical profession has been viewed with increasingly assertive scepticism which, it is suggested, has not always been constructive. It could well be feared that the classic 'intellectually bigotted' lay committee member might obstruct decision-making by the committee on ideological grounds rather than reasonable grounds. That, however, is a recognisable hazard which can be accepted within a well-structured framework.

Much depends on the model upon which research ethics committees are based. The danger of an adversarial model is that it can either render the decision-making process unworkable through members taking up defensive positions or it can force decisions to be made at the expense of dissenting opinions. This is a drawback of the climate within which the 1991 Department of Health guidelines were introduced - that is, a climate of "control" and "public scrutiny".⁵⁵ It is arguable that the guidelines themselves unwittingly fostered and nurtured defensiveness and distrust.

In order to fulfill their role effectively, lay members must be critical, they must question but not, however, to the extent of paralysing the decision-making process altogether. To avoid this, lay members as well as the other members ought to receive training which not only clarifies their role but also enables them to fulfil this role with the degree of

⁵⁵See fn 3 above.

flexibility which is required for a REC to work effectively. In essence, research ethics committees ought to be based on a model of mediation. This entails developing the procedures within which committees work so that, for example, decisions as to weight of opinion as well as measures for conflict resolution are devised.

5.2.1. VOTING PROCEDURES

The Department of Health guidelines do not include any provisions concerning voting procedures; this is considered to be a matter for the committees' discretion. Some committees reach their decisions by unanimity which, effectively gives every member a veto. Others employ majority voting which raises the question of what size must be the majority in order to carry the vote - a point on which there is no unanimity.⁵⁶

It is arguable that unanimous voting represents the highest ethical ideal. It can, however, act in such a way so as to force out a high proportion of proposals. This would undoubtedly inhibit the development of research which would affect patients to the extent that they might be deprived of the best quality of care. Furthermore, society might also be deprived of the possible benefits of medical progress. In effect, unanimity brings decisions down to the lowest common denominator of the sort of research to be approved. As a result, it is the members who like a protocol least who are accommodated. Hence, it is arguable that overall progress is minimal and the process may eventually be non-viable.

By contrast, majority voting ensures that some forms of research would be approved which would fail in the event of a member exercising his or her veto under the unanimity principle. However, it might be argued that such a system of voting is unethical in that a

⁵⁶Fieldresearch revealed that four committees used majority voting whilst three used unanimous voting. See Appendix E.

valid objection to a protocol can be overridden by a majority of members who may adopt equally inflexible positions.⁵⁷

A shortfall of the current system for regulating research is that RECs are not under the aegis of any higher organisation as regards their practices. What if, for instance, a REC or one of its members was particularly uneasy about a research protocol and feared that it might be offered elsewhere, especially if the protocol formed part of a multi-centre trial?⁵⁸ It is arguable that there would be a moral imperative to register its concern with a higher organisation.⁵⁹ Whether one believes that the route to further consideration would be to the Department of Health, the Scottish Office or to the General Medical Council, the fact remains that such a practice ought to become accepted as standard. This question was put to a selection of research ethics committees in Scotland by way of a questionnaire. None of the respondent committees had any procedure in place whereby they would contact any of the above mentioned bodies in the event of doubt concerning a research proposal. Indeed, a member of one committee answered that whenever a proposal raised issues to which he was opposed - as, for example, in the case of research involving the use of foetal materials - it was his practice to retreat from the deliberation process concerning that particular proposal. This is clearly unsatisfactory - research ethics committees staffed by doubting Pontius Pilates do nothing to inspire confidence in the efficiency of the review process as a whole.

The arguments in favour of unanimity and majority voting are, perhaps, equally persuasive. The main result of the discussion, however, is to raise issues concerning lack of uniformity as regards the practices of research ethics committees. Uniformity is particularly important in that it would also act as a deterrent to researchers hoping to

⁵⁷ An illustration of this point is to be found in European Community Law. The introduction of qualified majority voting in the Council for most internal market legislation (see art. 148 (2) of the EC Treaty) was a measure which was intended to ensure that the provisions for an internal market could be achieved in time for the 1992 deadline.

⁵⁸ Although it remains to be seen what effect the regional multi-centre RECs will have. Nicholson, fn 6 above at 23.

⁵⁹ This is a real concern given that some committees have reported that they were aware of research projects being undertaken according to protocols substantially different from those that they had approved. Nicholson, fn 6 above at 20.

resort to what has been referred to as 'committee shopping',⁶⁰ whereby researchers target RECs with less stringent standards and which are more likely to give their approval.⁶¹ This is a real concern, as a letter which was published in the *British Medical Journal* in 1995 indicates.⁶² Mr Dear, the chairman of a clinical research ethics committee at St James' University Hospital in Leeds disclosed a letter he had received from a major pharmaceutical company. The study in question concerned the comparison of antibiotics in the treatment of otitis media and chest infections in children to which the committee had refused to give approval on the advice of a consultant microbiologist. The committee contacted the company in order to outline their concerns.⁶³ The response they received included the following;

"Fortunately, there are sufficient LRECs [local research ethics committees] elsewhere in the country for us to be able to proceed with this study without the participation of Dr- as a trialist."⁶⁴

One wonders how far such a cavalier attitude extends in the pharmaceutical profession.

5.2.2. UNIFORMITY

The practices of research ethics committees vary from region to region.⁶⁵ It is, for example, common practice for research ethics committees to produce annual reports; but the quality of these varies. Nicholson found that over 45% of reports met DoH requirements for information contained in annual reports.⁶⁶ A sample of annual reports

⁶⁰Originates from the concept of 'forum shopping' in Private International Law.

⁶¹This obviously only follows if we accept the premiss that one method of reaching decisions is more restrictive than the other.

⁶²'Local research ethics committees and multicentre drug trials' (1995) 310 BMJ 735.

⁶³Grounds included the fact that the inclusion criteria were vague, most of the infections would be viral in origin, neither of the drugs reflected the then recommendation for treatment of such infections, the methodology which was proposed was poor especially as regards sampling and so on.

⁶⁴*Ibid.*

⁶⁵See Saunders, J 'LREC problems: a member's perspective' (1995) 112 Bull Med Eth 15.

⁶⁶Nicholson, fn 6 above at p. 15. The test was based on whether annual reports included information listed in para 2.16 of the DoH guidelines. For example, did they give the names of their committee members, did they list the number of meetings held and did they give a list of proposals considered with the outcome of such consideration. As regards composition, he found that, "Most committees, for instance, provided only the names of their members, and one barely glances at the list. A few

obtained from research ethics committees in Scotland revealed that their analyses of patterns of research, summaries of proposals and decisions taken differed markedly; in some cases it was extremely difficult to obtain an overview of the committee's practices.

A further disparity is that some committees have been known to endorse new research which was unnecessary and have acquiesced in under-reporting of unsuccessful research which they had approved.⁶⁷ In 1981, for example, Baum and his colleagues reported results of a review of controlled trials assessing the effects of prophylactic antibiotics on wound infection and mortality after colonic surgery.⁶⁸ Synthesis of the results revealed that the effectiveness of antibiotic prophylaxis in reducing morbidity and mortality had been conclusively ascertained by the mid-1970s. Yet, research continued into the 1980s despite the fact that these results had already been published. Five out of the seven RECs who responded to my questionnaires had measures in place for monitoring research proposals once approval had been given.⁶⁹ Nicholson found that most RECs do not have such measures, mainly because of the lack of resources. Of 173 committees from whom reports were received, 12 provided substantial evidence of knowing what progress, or lack of it, each approved research project had made.⁷⁰ There is a strong case to be made for establishing a body entrusted with auditing the work of research ethics committees.

5.2.3. INCREASED COMMITMENTS

The number of proposals which RECs are being asked to consider is rising steadily. The evidence supplied by four committees of their annual workload from 1982-1992 to

committees, however, provided potted biographies of their members, which were well worth reading. If, in addition, one includes members' ages and terms of office, the list becomes a complete and useful document." See p. 22.

⁶⁷Savulescu, J, Chalmers, I, Blunt, J 'Are research ethics committees behaving unethically? Some suggestions for improving performance and accountability.' (1996) 313 BMJ 1390.

⁶⁸Baum, M L, Anish, D S, Chalmers, T C, Sacks, H S, Smith, H, Fagerstrom, R M 'A survey of clinical trials of antibiotic prophylaxis in colon surgery: evidence against further use of no-treatment controls.' (1981) 305 N Eng LJ Med 795.

⁶⁹See Appendix E.

⁷⁰Nicholson, fn 6 above at 16.

Nicholson had experienced a four fold rise.⁷¹ In the period spanning the 1st October 1991 to 30th September 1992, for example, the Tayside Committee on Medical Ethics⁷² dealt with a total of 308 research proposals.⁷³ This represented an increase of 31 % over the previous year.⁷⁴ Between 1991 and 1995, the number of proposals submitted for approval rose from 193 to 311.⁷⁵ To combat this, the said committee considered doubling the number of meetings held per month together with the imposition of charges for studies sponsored by drug companies.⁷⁶

An increase in the submission of proposals poses administrative problems.⁷⁷ RECs sit on average once a month; it is questionable whether they have a sufficient amount of time or indeed resources to consider each proposal.⁷⁸ The larger the workload of the committees, the more proposals they review at each meeting.⁷⁹ How effective, then, are these committees given the restraints under which they operate?⁸⁰

5.3. THE IMPACT OF RESEARCH ETHICS COMMITTEES

The effectiveness of the Department of Health guidelines has been questioned. This has been achieved by assessing the impact of research ethics committees on the regulation of medical research.

⁷¹Nicholson, fn 6 above at p. 17.

⁷²Which is a joint committee of Tayside Health Board and the University of Dundee.

⁷³Tayside Committee on Medical Ethics, *Annual Report for 1995* at Appendix I.

⁷⁴The Ayrshire and Arran research ethics committee has seen an increase in its workload of 100 % since 1991; note, however, that it dealt with a total of only 31 proposals in 1993. See Ayrshire and Arran Research Ethics Committee *Annual Report for the Year 1 January 1993-31 December 1993* (1994).

⁷⁵See Tayside Committee on Medical Ethics, fn 73 above at 5.

⁷⁶Tayside Committee on Medical Ethics, fn 73 above at p. 2-3. Note that Nicholson found only fifteen committees which imposed charges on pharmaceutical companies. Nicholson, fn 6 above at 21.

⁷⁷While, A E 'Cross district comparison of applications to research ethics committees' (1995) 311 BMJ 661.

⁷⁸Cookson, J B 'Auditing a research ethics committee' (1992) 26 J R Coll Physicians Lond 181.

⁷⁹Nicholson, fn 6 above at 18.

⁸⁰Nicholson found that some committees used a so-called 'chairman's action' which involves the chairman of an REC approving some categories of research proposal between meetings, with the whole of the REC having the opportunity to ratify, or not, the chairman's action at a later meeting. See fn 6 above at 18.

Julia Neuberger stated in a report which she compiled for the King's Institute:

"...But over and above such recommendations is the clear recognition that there should be legislation on this subject. It is clear that RECs have not hitherto followed guidelines particularly closely. It is also clear that they lack power, being advisory to DHAs and other appointing authorities, and have no policing or monitoring role."⁸¹

To some extent, the effectiveness of RECs has been 'neutralised'. An interesting analogy can be drawn with the evolution of police accountability in the United Kingdom. The issue, which has generated substantial controversy, is what Reiner has described as,

"...the quasi-legislative and executive functions of determining the priorities and efficiency of force policy."⁸²

The duty of a civilian police authority is to 'secure the maintenance of an adequate and efficient police force for the area.'⁸³ They not only share policing costs with central government, but they also deal with issues concerning the force's establishment and rank structure, as well as appointing the Chief Constable. The main thrust of the 1964 Act is that it defines the responsibility concerning 'operational matters' as a matter for Chief Constables. In practice, however, a distinction has been maintained between 'operational' and 'policy' matters despite the fact that this distinction has no basis in the Act. In effect, operational matters are considered to be matters which are wholly matters for the police whereas policy matters are regarded as being issues to which members of the public can contribute. In summary, the public's role in the running and accountability of the police is limited. The same can be said as regards RECs.

The public interest issues with which research ethics committees are faced arise at the coal face or the micro-level. They include, *inter alia*, ensuring that adequate arrangements for obtaining consent from research subjects have been made, financial

⁸¹Neuberger, J *Ethics and Healthcare: The Role of Research Ethics Committees in the United Kingdom* (1992) at 8.

⁸²Reiner, R *The Politics of the Police* (1991) at 237.

⁸³The Police Act 1964, s 4(1).

recompense for volunteers and whether the research proposal constitutes unnecessary research; they also consider whether, for example, children ought to be used as research subjects. Macro-level issues such as the allocation of finance for research and the political moves within medical research are outside their remit. This may well be dictated by the lack of time. The issues which RECs do focus on are predominantly ethical and legal; scientific politics are not taken into account. This, as we saw in Chapter One, can be dangerous in view of the influence which governments and industry have on the pattern of research. One wonders whether this could have been the intention of the guidelines which, whilst appearing to underpin accountability, ensure that the 'grand design' of research remains relatively unscathed. This interpretation may appear too Kafkaesque; it does, however, contain a grain of truth. Due to the lack of time and resources imposed by their workload, RECs are conveniently 'distracted' from considering the wider issue at stake - they are more or less there to take on the responsibilities and to administer the general policies of higher authority. Like Charlie Chaplin in *Modern Times*, they struggle to turn the screws and cogs of the research machine whilst being unable to influence the design of the machine itself. This is not to say that research ethics committees ought not to have an administrative role but it *is* to say that they should have a role in policy making. Their experience at the coal face is invaluable as an indicator for the direction which research ought to take. They have a role in establishing norms for medical research.

Consider, for example, the Conquest of Cancer Campaign launched by President Nixon in the United States during the Seventies,⁸⁴ the aim of which was to find a cure for cancer.⁸⁵ The scientific administration which was directly responsible for planning the campaign - which included drafting the National Cancer Act - consisted of 250 scientists.

⁸⁴'State of the Union' Message. President Nixon, January 1971. See also Peart, W S 'Medical Research is too important to be left to the researchers!' (Lecture given at the Royal Institution, Albermarle St, London on 18 October 1973 to mark the 25th anniversary of the foundation of the Glaxo 1973).

⁸⁵The kind of scientific political thinking which this statement exemplifies was to some extent mirrored in the United Kingdom; the then Government, influenced by the apparent success of the Campaign in the United States, also decided to set up an inquiry of a similar nature, the results of which were published in the Zuckerman Report on Cancer Research in October 1972. See Zuckerman *Cancer Research: A Report by Lord Zuckerman* (HMSO 1972).

Many members of the scientific community were sceptical about politicians, administrators and scientists working so closely together. Their scepticism was echoed by the remarks of Dr O' Connor, the then scientific administrator and head of the 'Molecular Control Programme' of the National Cancer Institute, who said,

"Good science for its own sake, no matter how beautiful it is, will not get funded. Good research that may lead to cancer control, will."⁸⁶

The inherent danger which was so neatly summarised by Dr O' Connor is that involving the political establishment in medical research could, to a certain degree, shift the balance of availability of research for the worse albeit, supposedly, guided by the best of intentions.

"Has there ever been a real shortage of money in the field of cancer research, and are politicians in general and the public fully aware that it has been difficult to spend the funds available over decades effectively, and equally important, are they aware that there are cures for various forms of cancer?"⁸⁷

Directing vast amounts of research funds to a particular medical field can have the effect of starving other potentially worthwhile research projects of financial support. The importance of subjecting medical research to public scrutiny and debate cannot be overstressed, particularly in view of the large sums of public money which are spent in the field.⁸⁸ For example, in 1992-3, the Medical Research Council in the United Kingdom spent a total sum of £M219.01 on clinically related research from a total budget of £M253.3.⁸⁹ Whereas £M13.48 was allocated to cancer research, £M69.65, or 31.8 % of the total budget was spent on AIDS or AIDS related research.⁹⁰

⁸⁶'National Cancer Plan: The Wheel and the Issues Go Round' (1973) 179 Science 1305.

⁸⁷Pearl, fn 84 above at 12.

⁸⁸See Thompson, I E, French, K, Melia, K M, Boyd, K M, Templeton, A A and Potter, B 'Research Ethical Committees in Scotland' (1981) 282 BMJ 718.

⁸⁹Medical Research Council, *Annual Report* 1992-93 (1993).

⁹⁰The Annual Report states that the money was spent on "Molecular Structure, Metabolism, Cell and Tissue, Immune System, Skin, Inheritance."

Is this a just allocation ? It has been said that,

“There are now more AIDS workers than there are patients for them to treat. We do not feel there will now be a spread to the general community outside the accepted high-risk groups. We should be putting the money into areas where there is a true epidemic, such as heart disease and cancer, as well as life-spoiling diseases like mental illness and multiple sclerosis. There are too many people with a vested interest in keeping funding at its present unnecessary level...an AIDS industry has sprung up.”⁹¹

The AIDS budget of the World Health Organization (WHO) in 1995 was around \$M70. The Joint UN Programme on AIDS (UnAIDS) which was set up in January 1996 and which replaced the WHO AIDS programme is expected to receive approximately the same amount of funding.⁹²

One result of allocating too much money for AIDS research could be that spurious research proposals may be promoted in order to ensure the steady supply of research grants; in other words, unless the funds allocated for AIDS are spent, the same amount will not be awarded in the future. Is this the sort of factor which RECs ought to take into account when deliberating whether it will approve research proposals ? The potential for a government to gain votes by being seen to be doing something about an illness which finds itself at the forefront of national as well as international consciousness is considerable. It is doubtful that diseases such as arteriosclerosis or Alzheimers are as voter friendly.⁹³ RECs ought to be more aware of scientific politics and of the fact that their decisions have a socio-political impact.

In order to be aware of the public policy issues, members of research ethics committees must be informed of what the public, and through it the government, think about research. They must, however, also be able to inform the policy-makers of their own experiences at the coal face level. How can this be achieved in view of the opacity and

⁹¹Craven, B, *The Independent* August 8, 1994.

⁹²See *The Financial Times* May 5, 1995.

⁹³“We have said it before and it remains true today-the aged have few friends and they cast even fewer votes.” Mason, J K and McCall Smith, R A *Law and Medical Ethics* (4th edn, 1994) at 278.

of democratic deficit which ails the medical research process ? The next section addresses this question by considering the accountability of research ethics committees.

5.4. ACCOUNTABILITY OF RESEARCH ETHICS COMMITTEES

The accountability of RECs has attracted considerable criticism.⁹⁴ Traditional criticisms, however, are framed in terms of fault and blame - both of which are inherently adversarial - rather than of responsibility. Writing about the effectiveness of the DoH guidelines, for example, Mander uses the terminology of control by referring to “public watchdog”, “police standards” and “protection”:

“The question remains whether this definitive standard satisfies the LREC’s role as public watchdog. It is argued that it does not, as the guidelines do not provide the LRECs with any mechanism to enforce their recommendations and police standards. LRECs with the will and the resources will without doubt rise to the challenge and provide an effective service, within these limitations, but LRECs with lesser drive will not, without breaking their duty of care. The British public is therefore given a very unequal protection, which is arguably unethical in itself.”⁹⁵

Control, is, however, articulated through the tort of negligence which, as was argued in Chapter Three, provides a limited model of accountability. According to the tort of negligence, for example, each individual member of a REC could be held liable in tort for approving a trial in which a research subject took part and was damaged.⁹⁶ Mrs Wigley was just such a case. There is no evidence of the case having been taken to court but the inference of negligence is so strong that one feels that a case must have been settled out of court.

⁹⁴In particular see McHale, fn 37 above at 180 et seq.

⁹⁵Mander, T ‘The Legal Standing of Local Research Ethics Committees’ (1996) 2 *Medical Law International* 149 at 150. Note that the definitive standard to which Mander refers is one which is provided by the DoH guidelines and those provided by the European Union.

⁹⁶Brazier, M ‘Liability of Ethics Committees and their Members’ (1990) 6 *PN* 186. Note that the 1991 guidelines stipulate that members of research ethics committees who are NHS employees are covered by the NHS indemnity scheme. It further provides that other members, who are not NHS employees, ought to be covered by the district health authority unless the member concerned is, “guilty of misconduct of gross lack of care”. See fn 2 above at para 2.11.

As we saw in Chapter Three, however, the negligence model is too retrospective; it is an after the fact approach which relies on applying principles after the damage has been done. Principles governing medical research should be prospective. This demands an extension of the definition of accountability;

“It may be accountability to the committee, to the research subjects or to the law. Whilst these are by no means mutually exclusive, manifestly it is accountability to actual and future subjects which is critical.”⁹⁷

Thus, accountability not only concerns individual or collective legal liability to research subjects but also to the community in general. In a research ethics committee, a plethora of skills are united in one fairly democratic forum.⁹⁸ This calls for supervision, coordination and command at a number of levels; transparency is vital.⁹⁹ Possible ways in which this could be achieved are discussed in the next sections.

5.4.1. JUDICIAL REVIEW

The judicial review process provides a way of holding the executive to account. Its aim is to provide a remedy as well as improving the quality of public decision-making¹⁰⁰ and to ensure that such decisions are within the law.¹⁰¹

It is also educative insofar as it provides public authorities with principles and standards on which to base their own procedures.¹⁰² Judicial review may also be regarded as a tool of democracy. It has been used in cases brought against health authorities with reference

⁹⁷McClean, fn 47 above at 4.

⁹⁸See Galbraith, fn 9 above at 65.

⁹⁹Ibid.

¹⁰⁰See Lord Irvine of Lairg QC ‘Judges and Decision-Makers: The Theory and Practice of Wednesbury Review’ [1996] PL 59.

¹⁰¹For example, has the Secretary of State acted contrary to his statutory duty if an individual is deprived of medical treatment? *R v. Secretary of State for Social Services, ex parte Hincks* (1980) 1 BMLR 93.

¹⁰²Richardson, G and Sunkin, M ‘Judicial Review: Questions of Impact’ [1996] PL 79 at p. 103.

to decisions made as to the prioritisation of resources.¹⁰³ It has also been used as a lobbying tactic.¹⁰⁴ The law relating to judicial review in England must be distinguished from the position in Scots law notwithstanding that the grounds of review are the same in the two jurisdictions.¹⁰⁵ Thus, whereas the name of the procedure of judicial review is shared in both jurisdictions, the origin and content are not identical; there is no common system of judicial review in the United Kingdom.¹⁰⁶

An application for review can be made in relation to decisions of central government or any public authority or official.¹⁰⁷ It is not an appellate procedure but is a review of the legality of the decision. The grounds of challenge are those of illegality, irrationality and procedural impropriety.¹⁰⁸ If, for example, a researcher believed that his research proposal was dealt with in an unlawful or unfair manner or if a patient wished to challenge a decision taken by a REC to approve a research project, either could seek to hold a REC accountable for its decision by applying for judicial review on the grounds that the REC's decision was *ultra vires*.

There are, however, some formidable hurdles for an applicant to overcome. The first is the concept of *Wednesbury reasonableness* as defined in *Associated Provincial Picture Houses Ltd v. Wednesbury Corporation*, where it was held that;

“The Court is entitled to investigate the action of the local authority with a view to seeing whether it has taken into account matters which it ought not to

¹⁰³ As in *R v. Cambridge Health Authority, ex parte B* (1995) 25 BMLR 5 (QBD); 23 BMLR 1 (CA) for instance.

¹⁰⁴ See *R v. Inspectorate of Pollution, ex parte Greenpeace Ltd (No. 2)* [1994] 4 All ER 329, *R v. Secretary of State for Foreign Affairs, ex parte World Development Movement Ltd* [1995] 1 WLR 386 and also Harlow, C and Rawlings, R *Pressure Through Law* (1992).

¹⁰⁵ “There is no difference of substance between the laws of the two countries on this matter.” *Brown v. Hamilton District Council* 1983 SLT 397 at 414 per Lord Fraser of Tulleybelton.

¹⁰⁶ See Bradley, A W *The Laws of Scotland: Stair Memorial Encyclopaedia*, “Administrative Law” Vol 1 paras 345-400.

¹⁰⁷ See Halsbury's *Laws of England “Administrative Law”* Vol 1(1) at para 60 and also Wade, W and Forsyth, C *Administrative Law* (7th edn, 1994) at 668 et seq.

¹⁰⁸ As set out by Lord Diplock in *Council of Civil Service Unions v. Minister for the Civil Service* [1984] 3 WLR 1174 and recently followed in *R v. HM Coroner for South Yorkshire ex parte Stringer* (1993) 17 BMLR 92 at 114-115 where Turner J stated that, “It is of importance for all to understand that the relief which can be provided in this court is tightly circumscribed by the law which we have to apply. We can only interfere in cases of procedural irregularity, legal error or unreasonable decision.”

take into account, or conversely, has refused to take into account matters which it ought to take into account...once the question is answered in favour of the local authority, it may well be possible to say that, although the local authority have kept within the four corners of the matters which they ought to consider, they have nevertheless come to a conclusion so unreasonable that no reasonable authority could ever have come to it, and in such a case the court can interfere.”¹⁰⁹

It has been argued that decisions by public authorities are rarely overturned because their unreasonableness seldom achieves the *Wednesbury* standard.¹¹⁰ However, this argument may be misleading. Successful challenges concerning unreasonableness in the sense of irrationality are rare. Many decisions are, however, struck down on ‘lesser grounds’.

Be that as it may, the second - and, perhaps, fundamental - problem lies in the standing of the researcher or a research subject in respect of an application for review. Under English law, no application for review can be made unless leave of the court has been obtained.¹¹¹ The most important pre-condition is proof of “sufficient interest” in the matter on the part of the applicant.¹¹² There can be little doubt of this in the circumstances envisaged - the position is covered by statute.¹¹³ This is not merely a preliminary issue but is a matter to be resolved having regard to the merits of the case.¹¹⁴ Thus, standing is a necessary condition for a successful application - it is a ‘threshold question’.¹¹⁵ It will not, however, be sufficient of itself.

¹⁰⁹[1947] 2 All ER 680 per Lord Greene MR. This principle has also been accepted into the law of Scotland. See *Brown v. Hamilton District Council* 1983 SLT 397. See also Himsworth, C M G ‘Judicial Review in Scotland’ in Supperstone, M and Goudie, J (eds) *Judicial Review* (1992) 401 and also the *The Laws of Scotland: Stair Memorial Encyclopaedia*, fn 106 above.

¹¹⁰See Lairg, fn 98 above at 100.

¹¹¹Supreme Court Act 1981, s. 31 (3) and RSC Ord. 53, r.3 (1).

¹¹²See s 31 (3) of the Supreme Court Act 1981 which provides that, “the court shall not grant leave to make such an application unless it considers that the applicant has a sufficient interest in the matter to which the application relates”.

¹¹³Supreme Court Act 1981, s 31(3).

¹¹⁴*R v. Inland Revenue Commissioners, ex parte National Federation of Self-employed and Small Businesses* [1982] AC 617.

¹¹⁵Wade and Forsyth, fn 107 above at 708.

Generally speaking, the rules concerning standing have been progressively liberalised in England; the same may also be true in Scotland.¹¹⁶ For example, applications have been allowed by pressure groups when conventional tactics of political persuasion have failed. *R v. Secretary of State for Foreign and Commonwealth Affairs, ex parte World Development Movement Ltd*¹¹⁷ concerned an application by a non-partisan pressure group for a declaration that what they saw as a misapplication of public money was *ultra vires*. Neither the applicants nor its individual members had any direct personal interest of potential recipients of overseas aid. It was held, however, that they had sufficient interest given the importance of the matter and the prominent role of the applicants in giving advice, guidance and assistance.¹¹⁸ They were held to be acting in the public and parliamentary interest and were not, in the words of the court, “busy bodies, cranks or mischief-makers”.¹¹⁹ A clearer definition of a mischief maker was not offered by the court. Quite what the judges would have made of Henry Beecher, Jay Katz or Mr Hyman¹²⁰ is a matter for conjecture only. These individuals were not - as far as we know - cranks. Being a ‘busy body’ may well be part of the job description for being proactive in ensuring high standards of research practices.

Under English law, the applicant must show some substantial default or abuse. The position as regards locus standi differs in Scotland where the leave of the court is not required.¹²¹ The Scottish courts treat standing as a separate and preliminary issue¹²² but may, as in England, reject an application on its merits alone. It has been noted that there is less emphasis on a ‘private rights’ model and a movement towards an ‘affected

¹¹⁶See Wade and Forsyth, fn 107 above at 711 et seq. Munro, C R ‘Standing in Judicial Review’ SLT 1995 (News) 279 and also Mullen, T, Pick, K and Prosser, T *Judicial Review in Scotland* (1996) at p. 53. See also *Lakin Ltd v. Secretary of State for Scotland* 1988 SLT 780 (HL).

¹¹⁷[1995] 1 WLR 386.

¹¹⁸[1995] 1 WLR 386 at 393 F.

¹¹⁹[1995] 1 WLR 386 at 393 F.

¹²⁰See Chapter One, Section 1.5.1. et seq.

¹²¹An applicant must qualify title and interest to sue. See *The Laws of Scotland: Stair Encyclopaedia*, fn 106 above at para 308-232 and also *D and J Nichol v. Dundee Harbour Trustees* 1915 SC 7 (HL) as approved in *Air 2000 Ltd v. Secretary of State for Transport (No2)* 1990 SLT 335.

¹²²It is treated in most cases as “logically prior to and conceptually distinct from the merits”. See *Scottish Old People’s Welfare Council Petrs* 1987 SLT 179 at p. 184.

persons' approach.¹²³ It has, however, been argued that the law is potentially highly restrictive in relation to petitions by certain parties such as business competitors¹²⁴ and pressure groups.¹²⁵

The standing of the applicant is to be distinguished from a third hurdle - that is, the susceptibility of the REC to review. Much depends on the interpretation of the role of the REC. Research ethics committees are regulatory bodies but they derive their powers neither from statute nor from contract. Judicial review proceedings are appropriate - under English law - if RECs can be described as performing a public duty as this would make them subject to public law.¹²⁶ Research ethics committees act for and on behalf of the health authority and are, thereby, responsible for the regulation of all medical research involving human subjects within the NHS. As regards the duties of RECs, it has been stated that they,

“...derive from the central purposes of the Committee: to protect research subjects and maintain *proper standards of practice* in research, while ensuring that valid and worthwhile research is carried out.”¹²⁷

The REC has a duty to be properly constituted with specific rules governing its administration, which include the method of selection of members, maintenance of proper working practices, respect for confidentiality and the keeping of records of the decisions of the committee.¹²⁸ Much, however, depends on how ‘correct procedure’ is

¹²³Indeed, it was held in *Scottish Old People's Welfare Council Petrs* 1987 SLT 179 an interest to sue need not always be pecuniary. See also Munro, fn 116 above at 281.

¹²⁴See *Matchett v. Dunfermline District Council* 1993 SLT 537 and also *Hollywood Bowl (Scotland) Ltd v. Horsburgh* 1993 SLT 241.

¹²⁵It has been argued that litigation such as the *World Development* litigation in England has not been used in Scotland. See Mullen, Pick and Prosser, fn 116 above at p. 54. Note that the so-called *actio popularis* which exists in Scots law refers only to a person who is within a class of those entitled to enjoy a public right such as public rights to a pasturage, public rights to use of land for recreation or public rights of way. See *The Laws of Scotland: Stair Encyclopaedia*, fn 106 above at para 309.

¹²⁶See *R v. Panel on Take-overs and Mergers ex p Datafin plc* [1987] QB 815 where it was held that the duty owed by a body of persons must be a public duty if it is to be subject to public law. Hence, despite the City Panel on Take-Overs and Mergers having no formal legal status, it was held to be subject to judicial review because its functions accord with the nature and spirit of public powers and are indirectly maintained by statutory sanctions. See *Halsbury's Laws of England*, fn 107 above at para 64.

¹²⁷Kennedy, I ‘Research Committees and the Law’ in Kennedy, I (ed) *The Manual for Research Ethics Committees* (1992) at 5. (Own emphasis added).

¹²⁸McHale, fn 37 above at 180.

defined. The difficulty lies in the fact that no precise procedures are laid down. It is virtually impossible to make a direct comparison between RECs whose practices differ widely; there is no irregularity in this - it is a direct consequence of the flexible nature of the DoH guidelines which inherently allow for a diversity in working methods. Thus, the *Wednesbury* test as applied to the REC's decision would read as follows-was the decision so unreasonable that no other committee would have come to the same conclusion had it been acting reasonably ?

The procedure for judicial review in Scotland is provided by an Act of Sederunt (Rules of the Court of Session 1994).¹²⁹ The grounds for review are identical to those which exist under English law; Scots law has, however, distinctive features.¹³⁰ This is particularly apposite in relation to the accountability of the decisions of RECs. Different answers arise under Scots law due, particularly, to the flexible interpretation of the supervisory jurisdiction of the Court of Session.¹³¹

It was argued earlier that judicial review proceedings would be appropriate in relation to a decision by a REC in England in view of the element of public duty which attaches to its role and which is essential to a successful application. Thus, under English law, an applicant may only apply for judicial review providing the issue raised is one of public law. This position is not replicated under current Scots law. The so-called 'public / private divide' in Scots administrative law has been the focus of considerable judicial¹³² and extra-judicial¹³³ discussion. Scots law appeared to follow the English position until 1992,¹³⁴ This was, however, firmly rejected in *West v. Secretary of State for Scotland*.¹³⁵

¹²⁹SI 1994 / 1443, Chapter 58 replacing Rule 260B SI 1985 / 500.

¹³⁰ "[B]ecause the reviewing powers of the court in the two jurisdictions are built on different foundations, it is by no means inevitable that the same answers will be reached." See Himsworth, fn 109 at 405.

¹³¹Which is the forum for judicial review applications in Scotland. See fn 129 above. See Lord Kame's maxim in *Historical Law Tracts* (4th edn, 1778) at pp. 228-229 which states that it is the province of the Court of Session to *redress all wrongs for which no other remedy is provided*. [own emphasis].

¹³²See for example Lord Weirs's dictum in *Tehrani v. Argyll and Clyde Health Board* 1989 SC 342 at p. 350.

¹³³Lord Clyde 'The Nature of the Supervisory Jurisdiction and the Public/Private Distinction in Scots Administrative Law' in Finnie, W, Himsworth, C M G and Walker, N (eds) *Edinburgh Essays in Public Law* (1991) at 281.

¹³⁴See for example *Tehrani v. Argyll and Clyde Health Board* 1989 SC 342.

Mr West, a prison officer, sought to challenge by judicial review the refusal by the Scottish Prison Service to grant him removal expenses when he was transferred from one establishment to another. The court held that the issue between the parties was no more than a private dispute between an employee and an employer about the terms of his service. The challenge to the Prison Service's decision by judicial review on grounds of unreasonableness was held incompetent. In so doing, however, the court explicitly rejected the "public / private" distinction made under English law and substituted what has become known as the "tripartite test":

"The importance of this case for the present purposes is that it shows that the principle upon which the supervisory jurisdiction is exercised is not affected by distinctions which may exist for other purposes between public bodies and those who exercise a jurisdiction under a private contract. The public or private nature of the inferior body or tribunal is not decisive, nor is it necessary to inquire whether the decision of the inferior body or tribunal is administrative in character. The essential point is that a decision-making function has been entrusted to that body or tribunal which it can be compelled by the court to perform. As counsel for the respondent pointed out, the tri-partite relationship in these arrangements is significant."¹³⁵

Thus, the tripartite test dictates delegation of responsibility from one body to another. This would include, for example, a situation in which an employer delegates the power to decide to another body and the decision affects the employee;¹³⁷ the relationship between Mr West and his employer was, however, direct and therefore did not qualify. The tripartite test could be applied to RECs to the extent that Health Authorities delegate the power to decide to research ethics committees whose decisions affect researchers. As a consequence, researchers would have the power to challenge RECs. One is reminded of the case of *St Johnstone Football Club v. Scottish Football Association*¹³⁸ in which jurisdiction was extended beyond public officers or public bodies.¹³⁹ In this case, a football club brought an action against the Scottish Football Association Ltd in which a

¹³⁵1992 SC 385.

¹³⁶1992 SC 385 at 399-400.

¹³⁷"The common characteristic is not the nature of the tribunal or body as such but the entrusting to it of a decision-making power or duty which must be exercised within the jurisdiction conferred upon it and is accordingly subject to supervision by the court. *West v. Secretary of State for Scotland* 1992 SC 385 at 400.

¹³⁸1965 SLT 171.

¹³⁹And which was reaffirmed in *West*. See 1992 SC 385 at 390.

declarator was sought that a censure and fine imposed on them by the Executive and General Purposes Committee appointed by the association was illegal, *ultra vires* invalid and of no force and effect. The court upheld the challenge on the grounds that,

“...when a *quasi*-judicial tribunal is set up, albeit by a contract between private persons voluntarily entered into, with private jurisdiction, then since that tribunal must accept the obligation of conducting its proceedings in accordance with the rules of natural justice, the privative nature of the jurisdiction cannot be permitted to prevent the Court from stepping in to enforce those rules.”¹⁴⁰

It has been argued that local authorities accord well with the tripartite model¹⁴¹ in view of their practice of delegating much of their administrative work to committees and officers.¹⁴² A tripartite relationship was held to exist in *JDP Investments Ltd v. Strathclyde Regional Council*.¹⁴³ This case concerned a circular issued by the Secretary of State for Scotland to local authorities setting out non-statutory arrangements (“the Crichton Down Rules”) for offering back to the former owners surplus government land that had been acquired by or under threat of compulsion. Thus,

“The disposals to which the circular may apply include disposals of land previously acquired by the actual exercise of compulsory powers. Those powers of acquisition are ultimately derived from Parliament, their exercise in the case of local authorities ordinarily being authorised by the Secretary of State. At least in some circumstances the exercise of such powers will be amenable to judicial review. The 1992 circular and its predecessors issued by the Secretary of State do not impose statutory obligations but set, or in the case of local authorities commend, certain criteria for the disposal of surplus land. At least in circumstances where a local authority adopts the principles reflected in the circular, its purported application of them in a particular case falling within its terms may arguably, in my view, be the exercise of jurisdiction within the meaning of *West*.”¹⁴⁴

The case is particularly apt vis à vis the accountability of RECs insofar as the 1991 Department of Health guidelines - a circular - are the basis from which RECs derive their legitimacy. It appears, then, that the position under Scots law is clearer than that in

¹⁴⁰1965 SLT 171 at 175.

¹⁴¹See Finnie, W ‘Triangles as Touchstones of Review’ 1993 SLT (News) 51 at p. 54. The article also provides an insightful critique of the tripartite rule.

¹⁴²This is recognised by statute. See Local Government (Scotland) Act 1973, s 56.

¹⁴³1997 SLT 408.

¹⁴⁴1997 SLT 408 per Lord Hamilton at 413.

England; this must raise concern, if it is accepted that accountability of RECs should be uniform across the whole of the United Kingdom.

There are, however, difficulties with the tripartite test. It is not clear whether every decision involving the delegation by a party to a third party is reviewable. Moreover, it is unclear how the test is supposed to work beyond employment cases.¹⁴⁵ There are exceptions to the tripartite relationship. Thus, in *Watt v. Strathclyde Regional Council*¹⁴⁶ judicial review was held to be appropriate given the universal application of a decision reached by an Education Sub-Committee of the Strathclyde Regional Council to introduce revised arrangements for cover by teaching staff for absent colleagues.¹⁴⁷ The number of people directly affected by the authority's decision made the procedure appropriate - to paraphrase *West*, "the decision cut across statute".¹⁴⁸

The main anomaly which arises as a consequence of *West* must, however, be that the decisions of a health board can not be reviewed (as in the case of *Tehrani*)¹⁴⁹ but that decisions of a committee appointed by the health board to inquire into the petitioner's case would be reviewable because a jurisdiction had been delegated to it.¹⁵⁰

¹⁴⁵See Himsworth, C M G 'Public Employment, the Supervisory Jurisdiction and Points West' 1992 SLT (News) 257 at p. 261. Note that some judges have called for a guiding principle as opposed to the development of the tripartite relationship on a case by case basis. See *Blair v. Lochaber District Council* SLT 1995 406 per Lord Clyde at 410 L. In some cases, the third party has been held to be Parliament as the body which has conferred powers. See *Joobeen v. University of Stirling* 1995 SLT 120, per Lord Prosser at 122 G-H: "If the tripartite test is to mean anything, it cannot cover every case where one party has been created by another party. On the other hand, I think it must be acknowledged that sometimes a contract creates a new legal relationship, different from that of mere contracting parties. That is perhaps more likely where one of the parties has been created, with special powers, by Parliament or royal charter. The creation of a university, with members, seems to me to be an example of this." (Although in this case, it was held that the issue raised was one of contract and was not suitable for judicial review).

¹⁴⁶1992 SLT 324.

¹⁴⁷The teachers claimed that this contravened terms statutorily included in all their contracts following a national settlement agreed in 1987 under the auspices of the Scottish Joint Negotiating Committee for Teaching Staff in School Education.

¹⁴⁸1992 SC 385 at 411.

¹⁴⁹The case concerned a consultant surgeon employed by the NHS who had been suspended from duty following a complaint arising from his treatment of a patient. The health board investigated the allegations made against him and set up a committee of inquiry to investigate the allegations and report to the board.

¹⁵⁰If it is an employment issue. Himsworth, C M G 'Further *West* ? More Geometry of Judicial Review' 1995 SLT (News) 127.

There are no reports in the United Kingdom of any challenges having been made by way of judicial review concerning the decisions of research ethics committees. There is, however, an English precedent in which a decision by a *hospital ethics committee* concerning access to in vitro fertilisation (IVF) was questioned. The case, as the next section will show, illustrates the limitations of judicial review as an effective method of maintaining accountability of research ethics committees.

5.4.1.1. *R v. ETHICAL COMMITTEE OF ST MARY'S HOSPITAL (MANCHESTER), ex p H*¹⁵¹

It must be reiterated that *ex parte H* must be taken as illustrative only because there are no comparable cases involving a REC.¹⁵² Moreover, the establishment, composition and remit of a REC are clearly different from those of a hospital ethics committee. Thus, while the result might well have been different in the case of a REC, *ex parte H* is introduced here as doing no more than indicate some of the inherent shortcomings of committee control of medical practice. Looked at this way, it is highly relevant to the main thrust of this thesis.

In *R v. Ethical Committee of St Mary's Hospital (Manchester), ex parte H*, the applicant wished to be considered for IVF treatment under the National Health Service. The Infertility Service Ethical Committee advised that it was up to the consultant whether the treatment should be given. The committee ultimately decided that the applicant would not be eligible for IVF treatment, due mainly to the fact that several adoption agencies had previously refused to consider placing children with her in view of her criminal record, which included allowing premises to be used as a brothel and soliciting for prostitution.

¹⁵¹[1988] 1 FLR 512.

¹⁵²See also *R v. Sheffield Health Authority, ex p. Seale* (1994) 25 BMLR 1. See McHale, J, Fox, M and Murphy, J *Health Care Law: Text, Cases and Materials* (1997) at p. 672 et seq for discussion.

In seeking judicial review of the committee's decision, the applicant maintained that the decision was reached by the wrong body and that in the alternative, she was not given adequate opportunity to make representations to the decision-maker before the decision was taken. It was suggested that, once the committee had been asked for advice on whether a treatment should be given to a particular individual, it was obliged to investigate the matter and to give advice in pursuance to their deliberations. In refusing the application, however, Schiemann J held that the committee was entitled *not* to give advice, its main function being to provide a forum for professionals to talk things over and to provide general guidelines.

Two significant deductions may be drawn from the judgment. The first issue relates to the role of the committee. In the opinion of the judge, the role of the committee was advisory and it was not a decision making body. Schiemann J chose to rely on the committee's terms of reference which provided that,

“An Infertility Services Committee exists within the hospital. The committee was established in the spirit of the Warnock Report on Human Fertilization and Embryology. The Committee provides a forum for those who provide infertility services to discuss issues of concern and seek advice and guidance.”

There is, therefore, a distinction to be made between the hospital ethics committee and the REC. Applying Schiemann J's reasoning in the case the REC, having more than an advisory status, would be susceptible to judicial review.

We should also note briefly Ms H's contention that she was unable to make representations to the committee. The administrative load on a REC is considerable and nearly always exceeds the capacity of the clerical support available. This, combined with the absence of any directive on the subject means that the minutes of meetings with explanations of the decisions reached can be delayed almost indefinitely.

In the case of *ex parte H*, the committee met for the first time on March 15th. They met again on September 16th. The applicant's case was not cited in the minutes of the first

meeting,¹⁵³ despite the fact that there was evidence that it was discussed which was substantiated by an affidavit by a member of the committee. Without this affidavit, the applicant would most certainly not have had sufficient reason for bringing the case.

The applicant and her husband were eventually informed of the reason for the refusal of IVF treatment on September 20th, 1985 despite the fact that the decision not to treat the applicant had already been taken by the consultant in December 1984; Schiemann J criticised this as amounting to 'shadow boxing' in that the applicant was misled for a considerable length of time as to whether she would be treated or not. In effect, the odds were firmly stacked against her from the start. One can visualise the same process operating within a REC.

5.4.1.2. IMPROVING ACCOUNTABILITY THROUGH JUDICIAL REVIEW

R v. Ethical Committee of St Mary's Hospital (Manchester), ex parte H is an illustration of the ethical control of medicine at its worst. An Infertility Services Committee is, admittedly, not a research ethics committee but it is one set up to achieve the same ends - to ensure that the public is treated fairly and with due respect in circumstances where the patient is vulnerable to arbitrary decision-making. The case of Ms H exemplifies the working of a committee that is established on uncertain ground and which works under an uncertain remit. The difference between the Infertility Service Committee and a REC is, essentially, no more than one of administrative level. The lack of accountability which was so apparent in *ex parte H* exists also in the REC; it is because of the latter's wider range and standing that it is so important to learn the lessons provided by the former and to apply them throughout the committee system before a paternalistic and undemocratic system is accepted as the norm. What are clearly needed are laid-down procedures which clarify the hierarchy of accountability of ethics committees in general and research ethics committees in particular.

¹⁵³The entry in the minutes of the meeting was that, "...advice from the committee regarding individual patients was given, but is not minuted due to patient confidentiality" and further, "...it was emphasized that clinicians retained the right to decide upon treatment vis-a-vis their clinical judgment". [1988] 1 FLR 512 at 517.

The foundations of enhanced accountability ought to be the basic concept of democracy tempered by the principles of openness, transparency and reasonableness - which in the context of judicial review, can be seen as procedural fairness¹⁵⁴ - and demonstrated rationality or the obligation of a body to give reasons for its decision. The accountability of decision-making is to be achieved, in the words used in *West*, by upholding standards of rationality and fairness of procedures.¹⁵⁵

The discipline of a requirement for RECs to give reasons for their decisions is a good one as it ensures that standards according to which researchers are judged are exposed to public debate and scrutiny. The difficulty with which we are faced is the tradition in the United Kingdom of the professions being largely self-regulating. In the English case of *R v. Higher Education Funding Council*,¹⁵⁶ for example, it was held that a panel of academic specialists, whose appointed role was to assess and rate the quality of universities and other research institutions, did not have to give reasons for their decision to give the applicant institution a lower research rating. The emphasis in the judgment is very much in favour of peer review. Thus,

“We lack precisely the expertise which would permit us to judge whether it is extraordinary or not.”

And further;

“It is of course not for the court to advise an independent body on how to arrange and conduct its procedures.”¹⁵⁷

The court accepted, however, that there are classes of case where there is a duty to give reasons, namely, where interests are at stake which are highly regarded by the law such as personal liberty.

¹⁵⁴See *Tehrani v. Argyll and Clyde Health Board* 1989 SC 342 per Lord Weir at 351: “...there may be essential procedural requirements to be observed, and failure to observe them may result in a dismissal being declared to be void.”

¹⁵⁵*West v. Secretary of State for Scotland* 1992 SC 385 at 402.

¹⁵⁶[1994] 1 All ER 651.

¹⁵⁷[1994] 1 All ER at 670-671.

Be that as it may, the principles of rationality and accountability of decision-making are inherent in the remedy of judicial review which ought to provide the route to ensuring the legality of decisions taken. Indeed, these are the features, or *desiderata*, of accountability upon which the review process for medical research involving human subjects ought to be based. The conceptual flaw in judicial review lies, however, in the fact that the decisions are made by a person or persons who are unelected - namely, judges - and this applies throughout the process, from the original decision to allow or disallow an application to the final decisions as to the reasonableness of the administrative action. This may be unexceptional in, say, the commercial or political worlds but it is less than certain that it is desirable in such intimate matters as patient care. As I have argued in Chapter Three, judges are inappropriate as the final arbiters in respect of medical research.

Judicial review provides a potential procedure whereby researchers and their subjects can obtain satisfaction; but it is not necessarily the *best* procedure and I will offer alternatives in the following sections.

5.6. PROPOSALS FOR REFORM

5.6.1. A NATIONAL RESEARCH ETHICS COMMITTEE

Proposals for reform in relation to medical research have been made in the form of establishing a *national committee*.¹⁵⁸ It is arguable that the arguments in favour of a committee of this nature¹⁵⁹ have been taken up by the government in relation to multi-

¹⁵⁸Warnock, M 'A National Ethics Committee' (1988) 279 BMJ 1626. See also Alderson, P 'A national ethics committee?' (1995) 107 Bull Med Eth 13 and Scot Law Com No 151 at paras 5.70 -5.71.

¹⁵⁹Garfield, P 'Cross district comparison of applications to research ethics committees' (1995) 311 BMJ 661.

centre trials in Scotland which now has a national committee for multi-centre research.¹⁶⁰ A researcher must now submit a multi-centre research proposal to this committee which advises as to the science and general ethics of the proposal. It then forwards the proposal to the local research ethics committee for consideration of the issues which arise locally. England and Wales, however, have multi-centre research ethics committees in each region - there are no plans to establish a national ethics committee.¹⁶¹

Multicentre research projects have provided RECs with several administrative problems. First, they generate a substantial increase in workload because of the duplication of work; this affects RECs all over the country. Secondly, it affects the researchers insofar as each constituent REC will have different requirements; separate protocols may therefore be necessary with the added disadvantage that the researcher is unaware of the specifics outside his own area. Thirdly, if these trials were to be discussed in detail in every REC concerned, considerable delay may be caused with potential disadvantage to the subjects who would benefit from the research.¹⁶²

Aside from this, there is as yet no official move towards a National Research Ethics Committee which would have similar functions to local RECs but at a national level. Indeed, those who advocate a National Ethics Committee do not, in general, have this in mind. Rather, the intention appears to be to establish a body which would identify specific medical issues with major ethical implications and would elaborate a national policy on such issues.

There are many objections to such an organisation the most obvious of which is that it could not be responsible for national *policy*. A more likely solution is that parliament could be persuaded to continue in its present rather piecemeal approach of defining a problem and appointing a group to consider that particular controversial area. Such a group can then make recommendations which the government may or may not accept. If

¹⁶⁰'Multi-Centre Research Ethics Committee for Scotland' NHS Mel (1997) 8.

¹⁶¹'Ethics Committee Review of Multi-Centre Research' HSG (1997) 23. Note that Northern Ireland does not have any provisions concerning multi-centre research ethic committees.

¹⁶²See Montgomery, J 'Improving Review of Multi-Centre Trials' (1994) 95 Bull Med Eth at pp. 19-22.

it does, the next step is to legislate and to appoint an authority or committee to oversee the operation of the legislation. Thus, we have the Warnock Committee followed by the Human Fertilisation and Embryology Act 1990 and the corresponding authority; we have had the Kennedy Group on the Ethics of Xenotransplantation followed by the Xenotransplantation Regulatory Authority and, no doubt in good time, an Act of Parliament.¹⁶³ The process continues with increasing specificity - among others, Professor McLean's committee is considering post-mortem donation of genetic material and Professor Brazier's is looking at the aspects of surrogate motherhood. For my part, I would advocate a similar advisory group to study the implications of medical research.

This method has its advantages. The establishment of authorities provides an institutional framework which consolidates differing ethical positions into what was previously a purely medical forum. The aim of the authority is not only to monitor professional practice and to make the medical profession responsive to lay concerns but also, where appropriate, to achieve a consensus which provides clear and coherent principles for researchers. Secondly, it, so to speak, spreads the intellectual load among a wide cross-section of experts. Very few working academics can afford the time for membership of more than one committee; the more committees there are, the wider is the spread of the net that gathers in opinion.

Contrast this with the type of National Ethics Committee that has been advocated. Such a reform would, first, perpetuate the over reliance on the 'great and the good' but, this time in a centralised fashion. Effectively, such a Committee would be limited to relatively few people who might not even be representative of the academic field as a whole. There would be no justification for allowing such a group to speak *ex cathedra*.

Secondly, we have to ask whether we *want* an increase in the number of QUANGOs (Quasi-Autonomous National Governmental Organisation) to which we are subjected? Their formation has been widely criticised on the grounds that there is no democratic

¹⁶³The Human Organ Transplants Act 1989 was enacted too fast for an investigative committee to precede the establishment of the Unrelated Live Transplant Regulatory Authority.

accountability in the sense of democratic theory reflecting the collective will¹⁶⁴ - and that there is no public approval of their membership.

In point of fact, such has been the clamour for such an organisation that one has, already, been set up - albeit unofficially but with powerful backing. The Nuffield Council on Bioethics, established in 1991, is funded jointly by the Medical Research Council, the Nuffield Foundation and the Wellcome Trust. It is a non-governmental body whose terms of reference include identifying and defining ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern. It took on this role after it became increasingly apparent that there was no prospect of a similar governmental body being established. Thus, the Nuffield Council on Bioethics is essentially advisory rather than supervisory. It will give powerful advice but cannot command. As such it is a thoroughly useful body but in no way attains the stature envisaged by those seeking a national ethics committee.

What we are looking for in this thesis is the establishment of a regulatory body made on egalitarian grounds which is advanced as the correct rationale for the regulation for medical research. The next sections look upon this possibility by extrapolating from the concepts of Children's Panels and Citizens' Juries.

5.6.2. CHILDRENS PANELS

When the Children's Hearing System was brought into force in April 1971,¹⁶⁵ it was commonly regarded as a major innovation due mainly to its central feature - involving

¹⁶⁴“Quangos can now levy taxes; they can direct and take over industrial companies; and in some cases they can even interpret and enforce the law itself. Many of them are not answerable to Parliament for their activities, and many are not required to open their books to the Comptroller and Auditor General. Yet they disburse billions of pounds of public money.” Holland, P *Quango, Quango, Quango: The Full Dossier on Patronage in Britain* (1981). For a general discussion concerning Quangos see Craig, P *Administrative Law* (1989), Chapter Three Part 3, Lewis, N ‘Regulating Non-Government Bodies: Privatization, Accountability, and the Public-Private Divide’ in Jowell, J and Oliver, D (eds) *The Changing Constitution* (3rd edn, 1994) and Baldwin, G R and McCrudden, C (eds) *Regulation and Public Law* (1987), Chapter One.

¹⁶⁵Scottish Office Factsheet No 7 ‘Going to a Children's Hearing’.

members of the Scottish public in the decision making process within the juvenile justice system.¹⁶⁶ Each of the 32 local authorities in Scotland must establish a Childrens Panel¹⁶⁷ which deal with most cases of juvenile delinquency. The structure and operation of the Children's Hearing System was founded upon Part III of the Social Work (Scotland) Act 1968 and is now to be found in the Children (Scotland) Act 1995.¹⁶⁸ The system is centred on the welfare of the child, which is paramount; moreover, it is accepted that children should be treated in an equal manner whether they have committed an offence or whether they require care and protection.¹⁶⁹ Several groups are charged with the administration and the operation of the system - the Reporter to the Children's Panel, the Children's Panel Advisory Committee, and the social work department. The Children's Panel offers a model in several respects on which to found reformation of medical research ethics committees.

First, local authorities in Scotland are required by law to form a children's panel.¹⁷⁰ This is in direct contrast to the position of local health authorities vis à vis their obligation to establish research ethics committees, which is based on guidelines issued by the Department of Health. Secondly, local authorities in Scotland are obliged to publish a list of the names of addresses of members of the children's panel for their area; the list must be open for public inspection at all reasonable times.¹⁷¹ No such explicit provision exists in relation to research ethics committees.

Thirdly, the composition of these panels serves as an illustration of how broadly "lay member" can be defined. Generally speaking, Childrens Panels should comprise at least

¹⁶⁶"Members of the community are directly involved, not only those who serve as members of children's panels but also those who recruit and select them, and second, the fact that hearings deal with children from the standpoint of their needs." George Younger, the then Secretary of State for Scotland in October 1982 in Martin, F M & Murray, K *The Scottish Juvenile Justice System* (1982) in the Foreword.

¹⁶⁷Children (Scotland) Act 1995 s 39 (1). See also McK. Norrie, K *Childrens' Hearings in Scotland* (1997) at p. 7 et seq.

¹⁶⁸Chapter Two.

¹⁶⁹Rose, J *The Laws of Scotland: Stair Memorial Encyclopaedia*, "Children's Panels" Vol 3 para 1281.

¹⁷⁰Children (Scotland) Act 1995 Schedule 1 Para 1.

¹⁷¹Children (Scotland) Act 1995 Schedule 1 Para 12.

three members - at least one woman and one man.¹⁷² In particular, panel members should,

“have knowledge and experience in dealing with children and families and they should be drawn from a wide range of neighbourhood, age group and income group. They require the right personal qualities, including absence of bias and prejudice and genuine interest in the needs of children in trouble and their relationship with the community”.¹⁷³

They are not, generally speaking, selected from the professions. A study of the children's panel membership in Scotland was commissioned by the Children's Panel Chairmans' Group in 1992.¹⁷⁴ It found that, in general, panel members were above average in terms of education and upward social mobility. Eighty five percent were or had been married and 86% were parents.¹⁷⁵ There has been a significant fall in the number of high professionals and an increase in clerical and skilled manual workers.¹⁷⁶ About 45 % of panel members are classified as junior professionals (teachers, nurses and other welfare workers who work with children or disadvantaged families). There has been an adjustment down the social class scale, based on occupation, which makes the childrens' panel representative of the communities they serve.¹⁷⁷ A wide age, occupational, social and cultural mix has been discovered to be a realistic aim.

The aim of this section has not been to suggest that Children's Panels should in any way replace or, even, run parallel with research ethics committees. They do, however, indicate how RECs might be composed and the advantages of having this systemised.

¹⁷²Children (Scotland) Act 1995 s 39 (5).

¹⁷³Social Work Services Group Circular SW7/1969/App A, para 1.

¹⁷⁴Lockyer, A and Wilkinson, D *Citizens Serving Children: A Study of Children's Panel members in Scotland on behalf of the Children's Panel Chairman's Group* (1992) at 10.

¹⁷⁵Lockyer and Wilkinson, fn 174 above at 11.

¹⁷⁶*Ibid.*

¹⁷⁵Lockyer and Wilkinson, fn 174 above at 10.

¹⁷⁶Lockyer and Wilkinson, fn 174 above at 11.

¹⁷⁷*Ibid.*

5.6.3. CITIZENS JURIES

We have seen that the Children's Panel provides a model which will do little more than exemplify some changes which might well improve the function of the REC; the Citizens' Jury, by contrast, is built on a format which may well be developing as a popular forum in its own right and one which could be harnessed to the REC with considerable public advantage.

The idea behind citizens' juries is for an appropriate authority¹⁷⁸ to select small groups of citizens from the general public to deliberate questions on a range of policies - which could include planning, health care provision, education and the like.¹⁷⁹ They are based on the concept of participatory democracy which is defined as including suitable representatives of the general public.¹⁸⁰

It is not envisaged that they would provide decisions. Rather, they would lay the foundations for a consensus by constituting a network of communicating information and points of view which would could be filtered and synthesised so as to represent specified public opinion. It is important to grasp the role of experts is not overridden or undermined; rather, it is qualified. Thus, planning and decision-making is shaped by deliberative politics, that is:

"shaped by the publicly organized contest of opinions between experts and counterexperts and monitored public opinion."¹⁸¹

¹⁷⁸In the United Kingdom this may well be the local authority.

¹⁷⁹The idea was developed by Professor Peter Dienel of the University of Wuppertal in Germany and Ned Crosby of the Jefferson Center in Minneapolis, USA. See Stewart, J, Kendall, E, Coote, A *Citizens' Juries* (1994).

¹⁸⁰This is of course an innovation. Currently "There is no accepted place for active citizenship within Britain's system of government. Passive citizenship is assumed and thereby encouraged." Stewart et al, fn 179 above at 3.

¹⁸¹Habermas, J *Between Facts and Norms: Contributions to a Discourse Theory of Law and Democracy* (1996) at 351.

The emphasis is on local knowledge¹⁸² and the aim is to foster and build a new habit of citizenship. There is a great emphasis on juries being unbiased whilst bringing their experience and understanding which is not "...otherwise available to government 'experts'".¹⁸³ The model allows for deliberation of a wide spectrum of opinion.¹⁸⁴

In Germany, citizens' juries have developed as planning cells (*Planungszellen*) and are commissioned by Professor Dienel's research institute on behalf of local or national government bodies. The Institute works within the federal state system. The sponsoring organization funds the project and contracts to undertake to take the juries' conclusions into account. Indeed, proposals suggested by planning cells are frequently implemented.¹⁸⁵

In the United States, Citizens' Juries are organised by the Jefferson Centre and have been used in a variety of contexts including President Clinton's health care reforms, at national level, and welfare policy and teenage crime at state level. In direct contrast to the position in Germany, the Centre is an independent organisation, paid for and run by Crosby.¹⁸⁶ It is of interest to note that the original idea resulted from his Ph.D. at the University of Minnesota where he saw the Citizens' Jury as a solution to fundamental problems of democracy - indeed, to the manipulation of the public by political parties,

¹⁸²As opposed to misconceived government initiatives; "...university campuses on bleak parklands miles from city life, designed with little practical knowledge of students' needs and desires; medical training and hospital organisations developed with little knowledge of the particular concerns of women; transport systems worked out as if children did not exist; employment legislation passed as if the passing was enough, and the implementation could be left to the courts, without thought that the knowledge of the workers affected should be built in;" See Wainwright, H *Arguments for a New Left* (1993) at 279-280 cited in Stewart et al, fn 179 above at 3-4.

¹⁸³Stewart et al, fn 179 above at 6.

¹⁸⁴"Deliberation is the process by which different views are tested and arguments are advanced to persuade. It involves discourse about an issue and reflection on what is said. Through deliberation new possibilities can be opened up and differences reconciled. If one seeks to persuade then one has to take account of views other than one's own. Representative democracy can be enhanced by deliberation amongst citizens." Stewart et al, fn 179 above at 6.

¹⁸⁵Stewart et al, fn 179 above at 1.

¹⁸⁶See fn 179 above.

the corruption of government decision-making by special interests and the failure of voting to ensure real democracy.¹⁸⁷

The introduction of Citizens' Juries in the United Kingdom has received support from several quarters¹⁸⁸ including the Institute for Public Policy Research (IPPR). In its report, "*Citizens' Juries*", the IPPR suggested that juries could deliberate on issues which include *inter alia* transport, childcare, community service, health care spending and education at both local and national level. Funding could be provided from a number of sources including public governmental bodies, political parties, the media or voluntary organisations. Indeed, the Labour Party has promised to consider the possibility of their introduction.¹⁸⁹ The south London borough of Lewisham spent £23,000 assembling 16 locals to debate drug education and treatment options. The criteria for selection included gender, housing, work, ethnicity and class. The results showed that the jury was representative of people in the borough. In another case, Walsall Health Authority used a citizens' jury to deliberate on the issue as to whether they should open a hospice.¹⁹⁰ Citizens Juries have also been used to consider questions such as the legalisation of cannabis.¹⁹¹

Enthusiasm for the prospect must, however, be qualified. In both the United States and Germany, the sponsoring body decides the issue to be addressed, defines the question and briefs the jury. It provides the jury with the information, selects witnesses and provides a moderator who acts as a time keeper and a referee.¹⁹² It is the moderator's responsibility to prepare the final report. Jurors may comment on the report and make recommendations and are allowed, in some instances, to amend their brief; they can also call on new sources of information. Thus while opinion making is very much a matter for the juries, power is nevertheless vested in the sponsors rather than in public bodies.

¹⁸⁷Stewart et al, fn 179 above at 1.

¹⁸⁸Lenaghan, J, New, B, Mitchell, E 'Setting priorities: is there a role for citizens' juries?' (1996) 312 BMJ 1591.

¹⁸⁹See *The Guardian* October 16th, 1996 at p. 11.

¹⁹⁰See fn 191 below.

¹⁹¹*The Times* November 11, 1996.

¹⁹²Stewart et al, fn 179 above at v.

In addition, in both Germany and the United States, the organisers and the sponsors hold the purse strings which increases their control. There is a very definite danger that so called Citizens' Juries become the mouthpieces of the sponsors rather than of the public.

A further problem concerns responsibility for provision of information to the jurors. Which party or individual should have this basic control? Limiting the provision of information to one party may give rise to selective presentation. The media have played a crucial role in the medico / legal debate. There is nothing wrong with this so long as the media, themselves, represent a fair cross section of public opinion. It is, however, doubtful whether this ideal is reached in relation to medico / legal problems which are highly emotional in character and tend to be reported uniformly. Whether this is a healthy method of informing the public deserves a short discussion.

5.7. INFORMING THE PUBLIC: THE ROLE OF THE MEDIA

5.7.1. SELECTIVE PRESENTATION

The medical profession and the legal profession are not the only people who tailor information to suit certain ends. The coverage of the *Child B* case¹⁹³ can be used to illustrate the way in which public perception can be shaped when provided with limited and partial information.¹⁹⁴ The case concerned the father of a girl with leukaemia who took Cambridge Health Authority to court for refusing to fund chemotherapy and a second bone marrow transplant for her in the public sector. Universally, the media gave minimum consideration to the clinical circumstances and the case was presented simply as an example of rationing based on financial considerations. Only five out of sixteen editorial articles mentioned the possibility that the proposed treatment might cause more

¹⁹³This has been officially reported in *R v. Cambridge Health Authority, ex parte B* (1995) 25 BMLR 5 (QBD); 23 BMLR 1 (CA).

¹⁹⁴Entwistle, V A, Watt, I S, Bradbury, R, Pehl Lesley, J 'Media coverage of the Child B case' (1996) 312 BMJ 1588.

harm than good and few emphasised that most medical experts felt that it was not the best course of action.¹⁹⁵ Reports of the chances of success varied; palliative care was mentioned sparingly, thereby reinforcing the belief that the alternative to the treatment sought was no care at all.

Further bias was shown by the way in which the experimental status of the treatment was examined. Whereas the Court of Appeal referred to the case as being at the “frontiers of medical science”,¹⁹⁶ the Daily Mirror devoted an article which attributed the current leukaemia cure rate to “brilliant research”; only through further research, impliedly by treating Child B, would better combinations of drugs and ways to reduce the side effects be found.¹⁹⁷ It cited the UK Children’s Cancer Study Group and the 20 major centres treating childhood cancer in Britain and stressed the need for “coordinated research” whilst failing to mention that the group, itself, had advised against the proposed treatment of Child B.

Several conclusions may be drawn. First, whilst the importance of medical expertise was acknowledged on the one hand, and the views of the family in respect of individual treatment decisions were focussed upon on the other, very little was written which would explain the basis of disagreements which must inevitably occur from time to time. Secondly, the coverage gave the impression that doctor’s decisions are always dominated by cost considerations. Thirdly, the coverage of the case was emotive, referring to the child as “Little B” or “Little Miss B”, displaying a tendency to seek preferential treatment for children on the basis of little more than sympathy.¹⁹⁸

¹⁹⁵Entwistle et al, fn 194 above at 1588; “The basic positions adopted in leader articles were generally reflected in the news reporting of each paper. Opposing viewpoints were included but tended to be marginalised, appearing on letters pages, in columns, or as other first person opinion pieces”.

¹⁹⁶*R v. Cambridge Health Authority, ex parte B* 23 BMLR 1 at 8.

¹⁹⁷Entwistle et al, fn 194 above at 1589.

¹⁹⁸Entwistle et al, fn 194 above at 1590.

The coverage of the Child B case raised three further issues. First, an interesting parallel was drawn in the *News of the World* with another case of parents whose child died of leukaemia and who were tortured with guilt after reading about Child B:

"I keep asking myself if they let Sharon die because of the money as well. Child B's father had the guts to find out why they were stopping her treatment. I didn't. I never questioned it. I accepted it. But it makes me feel now that if I'd done what he's done would I have got the same answer, 'We can't afford it? It's really bugging me. Did I let my daughter die without at least finding out what chance she had and what I could do about it?... You accept what doctors tell you because they are the experts and you trust them. Now I can't help asking if I did the right thing.'"¹⁹⁹

This is a point of fundamental importance as it touches upon why people take doctors to court. In the culture of blame, it is a way whereby people can obtain catharsis of a complex mixture of feelings of powerlessness, grief and pain; this is truly apposite to the workings of RECs insofar as experimental cases such as that of B will come increasingly within their remit. Are they to cover themselves legally by agreeing to experimental treatment which they know, in their hearts, to be inappropriate?

Secondly, the case highlighted the fact that we are living in an age of soundbites which tend to be focussed on the least admirable aspects of decision-making. The headlines in the Child B case included "Condemned by bank balance" (Sun, 11 March 1995), "A Price too high to pay" (Daily Mirror, 11 March, 1995) and "The idea that the medical judgement of a health authority can be clouded by financial considerations is distasteful and obscene" (Sun 11 March, 1995).²⁰⁰ This is coupled with the phenomenon of tabloidisation or the disappearing frontier between the 'quality' and the popular press and where foreign news, parliamentary reporting and investigative journalism is replaced by "what happened on the way to Sainsbury's".²⁰¹

There is a hidden assumption, however, that the quality broadsheets are intended to deal with different matters than do the tabloids or, if they cover the same subjects, they

¹⁹⁹Entwistle et al, fn 194 above at 1590.

²⁰⁰Entwistle et al, fn 194 above at 1588.

²⁰¹See *The Guardian*, G2 section, October 3, 1996 at 2 - 3.

should do so on a higher plane.²⁰² The erosion of considered media opinion is such that the public is nowadays presented with few alternative views and circulation figures are a poor basis on which to inform the public on questions of medical research.

5.9. CONCLUSION

It is a reasonable assumption that research ethics committees are desirable - or possibly essential - for the control of research and the protection of research subjects. What we have seen is that the model as has evolved in the United Kingdom fulfills its purpose less than ideally. We have discussed the reasons for this which include, *inter alia*, an ad hoc approach by individual committees to their role and practice and a general over-reliance on the expert culture. An essential tenet of this thesis is that public participation should be more widespread in what is a matter of public interest. This, however, implies that the public must be better informed. We have looked at some possibilities along these lines but it is now necessary to consider actual alternatives which are already in place elsewhere. The next section addresses this with reference to Germany.

²⁰²“Most of our readers have the capacity to think more broadly than that. They want to know about the single currency and they would be cheated if the Guardian didn’t give that. But they also want to know about Liam Gallagher and Patsy Kensit.” See fn 201 above at 3.

CHAPTER SIX

RESEARCH ETHICS COMMITTEES IN GERMANY

“Dennoch ist die Differenzierung zwischen Experten und Laien unhintergebar, und im Hinblick auf die dominanten Muster der gesellschaftlichen Produktion und Verteilung von Wissen sowie der Generierung von gesellschaftlichen Problemlösung kann man zu Recht von einer «Expertenkultur» sprechen.”

Leonhard Hennen¹

INTRODUCTION

The German Drugs Code (AMG), as amended in 1994, provides that research proposals must be submitted to research ethics committees, or *Ethik-Kommissionen* (EK), which are established at a regional level.² The committees are set up according to *state* law as opposed to *federal* law. Placing *Ethik-Kommissionen* on a statutory footing has ensured that their role has developed beyond being purely advisory. Prior to the 1994 amendment, questions had arisen regarding the nature of their function. Opinion was divided; some maintained that committees should be concerned only with the ethical implications of research proposals whilst others argued that they be also concerned with the legality of proposals.³ Moreover, they were fiercely criticised for being “alibi institutions” meaning that, whilst appearing to regulate medical research involving human subjects they were, in fact, ineffectual.⁴

¹The difference between experts and lay people is undecieving with regard to the dominant model of the societal production and distribution of knowledge as well as the generation of societal problem-solving; it is legitimate to speak of an «expert culture».” Hennen, L ‘Experten, Laien und Politik’ in Kolb, S (ed) *Fürsorge oder Vorsorge ?* (1996) at p. 158.

²According to the fifth amended version of the Arzneimittelgesetz (AMG) from 19. 10. 1994, BGBl. 1994 I. 3018 which has been in force since August 17, 1995. See § 40 Abs. 1 Satz 1 Nr. 6 AMG.

³Sobota, K ‘Die Ethik-Kommission-Ein Institut des Verwaltungsrechts?’ AöR 1996, 229 at 234 et seq.

⁴See Daele, van den W and Müller-Salomon, H *Die Kontrolle der Forschung am Menschen durch Ethikkommissionen* (1990) at 75-83.

The practice of *Ethik-Kommissionen* has provided mixed results. Despite, for example, the existence of detailed regulations concerning their establishment,⁵ there is little guidance as regards questions of procedure. Mirroring the position in the United Kingdom, the composition of research ethics committees is inherently professional with lay members being selected with reference to a professional benchmark; this has raised some concern.⁶

So too have the cases of unethical research which have arisen despite the presence of strict controls. A case which arose in 1990 and which was publicised in the *Süddeutsche Zeitung* is a prominent example.⁷ In this instance, a criminal charge was brought by the Humanistic Union against the director of a Psychiatric Hospital of the Ludwig-Maximilians University for experiments which were carried out at the clinic and which had received the approval of the University's research ethics committee. These involved subjecting in-patients to videos which contained frightening scenes in order to test the possible side effects of a particular medication which was reputed to cause panic attacks. The patients were unaware that they were research subjects.⁸ A further example is that of the "crash-test corpses" case which arose in Heidelberg in 1994. In this case, corpses which had been donated to the university clinic for research purposes were used in crash-tests of cars in lieu of dummies. Although this is logically an acceptable protocol - given that consent had been obtained - there was a public outcry once the details came to light.⁹ The trial had received the assent of the local research ethics committee which clearly did not represent local opinion.

⁵See Nordrhein -Westfalen (§ 6a HeilBerG) and Baden-Württemberg (§ 4a KammerG). The regulations empower the state physicians' chambers, the universities in particular, to establish the committees, to determine its duties, its composition and its rules of procedure. See Deutsch, E 'Die Bildung von Ethik-Kommissionen nach § 40 AMG' VersR 1995, 121 at 123 et seq.

⁶Hennen, fn 1 above at 158 et seq and also Daele, van den and Müller-Salomon, fn 4 above at 19-23.

⁷23.1.90 at p. 13, "*Strafanzeige...gegen die Mitglieder der Ethik-Kommission.*"

⁸The state prosecutor (*Staatsanwaltschaft*), decided there were insufficient grounds to prosecute.

⁹'Bald Crash -Tests mit Leichen' *Der Tagesspiegel* October 18, 1994. See also Sobota, fn 3 above at 237.

History plays its part in ensuring that there is a heightened sensitivity regarding questions of medical research in Germany. The awareness of the past ensures the issues raised are often the subject of public debate. This is, perhaps, a reflection of Germany's great post-War democratic tradition. Indeed, Citizens' Juries or *Planungszellen*, for example, were not only partly devised by a German academic¹⁰ but have been operational in Germany for many years allowing for the realisation of participatory democracy.¹¹

It is arguable that medical research in Germany is over-regulated. This criticism, as this next section will show, is not entirely justified - indeed, the AMG has been described by some as being too soft.¹² For example, whilst EK have the power to turn down a proposal, a trial may still go ahead if it receives the approval of the federal supervisory body, the *Bundesinstitut für Arzneimittel und Medizinprodukte* (BfArM) which is responsible for supervising the distribution of new medications onto the market.¹³

The position in practice is that a trial is unlikely to go ahead if it does not receive the approval of a research ethics committee as journals will not accept the results for publication.¹⁴ This is also the position in the United Kingdom; what, then, are the advantages, if any, of the German model ?

¹⁰Dienel, P *Die Planungszelle* (1991) and also Stewart, J, Kendall, E, Coote, A *Citizens' Juries* (1994).

¹¹*Planungszellen* have not, however, been used in relation to medical research.

¹²See below.

¹³See § 21 Abs. 1 S. 1 AMG which corresponds to medicines which are ready for distribution. Note that the BfArM is responsible for the general distribution of medical products. See the *Medizinproduktegesetz* (MPG) of 12. 8. 1994 BGBl. I, 1963 and also Lippert, H-D and Strobel, E-S 'Die Überwachung klinischer Prüfungen nach dem AMG' VersR 95, 637.

¹⁴Sobota, fn 3 above at 236.

6.1. RESEARCH ETHICS COMMITTEES (*ETHIK-KOMMISSIONEN*)

6.1.1. REGULATORY FRAMEWORK

The concept of the research ethics committee was directly transplanted from the United States into the German system.¹⁵ In effect, research involving human subjects is conducted in clinics and hospitals under the auspices of the *Ärzttekammern*.¹⁶ These *Ärzttekammern* have a duty to protect the public and to maintain the quality of medical standards.¹⁷ As in the United Kingdom, *Ethik-Kommissionen* exist both in the public and private sector.

6.1.1.1. RESEARCH IN THE PUBLIC SECTOR

The responsibility to set up *Ethik-Kommissionen* at a regional level is that of universities and the *Ärzttekammern*; these are public research ethic committees and act on behalf of the State.¹⁸ University committees are established and run by the senate, the faculty or the director of the clinic.¹⁹ *Ärzttekammer*²⁰ may set up a sub-committee or a regional (*Land*) committee.²¹ Their regulatory framework is to be found in codes which are drawn up by each *Kammer*, or chamber.²²

¹⁵Pichlmayer, R and Nagel, E 'Aus der Arbeit der Ethik-Kommission der Medizinischen Hochschule Hannover' in Benzenhöfer, U (ed) *Herausforderung Ethik in der Medizin: Beiträge aus der Medizinischen Hochschule Hannover* (1994) at 36. In direct contrast to its anglo-saxon counterparts, however, Germany did not transplant hospital ethics committees into its health service.

¹⁶The term *Ärzttekammer* translates literally as State Physicians Chamber and is used to refer to public bodies which are to be found at state and at a *Land* level. The *Kammer* produce professional codes of conduct which are recommendations only; these are not law although they are legally enforceable. Analogous bodies would be the General Medical Council (GMC) in the United Kingdom and the State Medical Boards in the United States. See Rieger, H-J *Lexikon des Arztrechts* (1988) at 1.

¹⁷See VGH Mannheim 6.6.1991 *NJW* 91 2368 at p. 2369.

¹⁸See the professional code of conduct for doctors § 1 (4) *Berufsordnung für Ärzte* (BOÄ).

¹⁹Their legal framework is to be found in the *Hochschulgesetze* of the individual *Bundesländer*. See for example the *Hochschulgesteze für Niedersachsen* § 115 (2) Nr. 1 i. V. m. § 95 (6) NHG.

²⁰Laufs, A *Arztrecht* (5th edn, 1993) at 7.

²¹Deutsch, E *Arzt und Arzneimittelrecht. Eine zusammenfassende Darstellung mit Fallspielen und Texten* (2nd edn, 1991) at 302-303.

²²See for example the Statute of the Saarland *Ärzttekammer* v. 27. 4. 1983, *Saarl. ÄBL* 1983, 334.

6.1.1.2. RESEARCH IN THE PRIVATE SECTOR

So-called 'free' *Ethik-Kommissionen* (*Freie Kommissionen*) evolved owing to the delay which often affected state committees in dealing with a proposal.²³ These committees are commonly found in private hospitals²⁴ or under the auspices of pharmaceutical companies.²⁵ They are not governed directly by the professional code of conduct drawn up by the State Medical Council (BÄK). Their practices are greatly influenced by the US Food and Drug Administration (FDA) guidelines which provide that a new medicinal product may only be released onto the American market if it receives the approval of an institutional review board (IRB) at the clinical trial stage.

Free committees are supervised at an international level. A European Ethical Review Committee is based in Rotterdam and there is also an International *Ethik-Kommission* in Freiburg which was established in 1980 and which is made up of various pharmaceutical companies.²⁶ The Freiburg Committee operates within the parameters set by the Basic Law as well as the professional codes of conduct, the Declaration of Helsinki, the German Drugs Code (AMG) and the FDA guidelines.²⁷

Freie Kommissionen are based on the Institutional Review Board (IRB) model; however, they differ greatly in terms of substance and procedure. Whereas free committees may be called upon to give their opinion as to the ethical validity of a proposal, their opinions are informal. They are advisory as opposed to supervisory; the status of advice is that which is to be expected from any private individual.²⁸ Consequently, they must not be confused with the public *Ethik-Kommissionen*.

²³Free committees, for example, traditionally reached decisions by members ticking one of three boxes on a printed approval form. This included the option of adding a few perfunctory remarks. See (1994) 344 *Lancet* 398.

²⁴An example of which would be the Städtische Kliniken, München.

²⁵For example Schering AG Berlin or Ciba Geigy GmbH, Tübingen.

²⁶This also includes British and French members.

²⁷See Laufs, A and Reiling, E *Ethik Kommissionen-Vorrecht der Ärztekammern ?* (1991) at 18-19.

²⁸Deutsch E 'Die rechtlichen Grundlagen und die Funktionen der Ethik-Kommissionen' *VersR* 89, 429 at 431.

The independence of such committees has caused much controversy in view of what some see as the commercial hidden agenda. After all, the main interest of a pharmaceutical company is to ensure that it can compete in a market tailored by highly competitive forces. Thus, a company may attempt to cut corners in seeking the approval of a free committee; indeed, they have been criticised as being no more than a form of consultancy service.²⁹

We will confine discussion to the public sector in view of the fact that the operation of the free committees is scarcely discussed in the relevant literature.

6.2. THE PRACTICES OF ETHIK-KOMMISSIONEN

6.2.1. ROLE

The role of the public *Ethik-Kommissionen* is to assess the ethical and the legal implications of research proposals with the collateral aim of protecting the subjects and the researchers. The committee must have regard to the general principles of constitutional law, in addition to the particular legal provisions and the codes of conduct of the professions concerned. The guidelines drawn up by the German Medical Association (BÄK)³⁰ provide that a committee must take the reputation of the institution under whose auspices the research is carried out into account and the effect which dubious research would have on the direction of research as a whole.³¹

In practice, the role of *Ethik-Kommissionen* is non-specific; it is a matter of opinion as to whether they are purely advisory, supervisory or possibly managerial.³² Academic

²⁹See Deutsch, fn 21 above at 299.

³⁰Bundesärztekammer Empfehlung zur Errichtung von Ethik-Kommissionen 1979 in Deutsch, fn 21 above at 298.

³¹See Deutsch, fn 21 above at 301.

³²Academic opinion in favour of dropping the name "ethik" altogether in view of the fact that their role is supervisory rather than advisory. See Sobota, fn 3 above at 229.

opinion takes the view that they are supervisory in view of the provision as contained in the German Drugs Code (AMG) which stipulates that a researcher *must* submit a research proposal to an *Ethik-Kommission*.³³ This is clearly the correct interpretation; Accordingly, the uncertainty surrounding the role of these committees is less than in the United Kingdom in view of the statute which specifically establishes a duty to submit research proposals. However, the role of the committees is not as fixed as those established by the statutes regulating research involving animals and genetic engineering.³⁴

6.2.2. THE DECISION-MAKING PROCESS

Ethik-Kommission in Germany reach decisions by majority voting. The committee must communicate its decision to the researcher in writing.³⁵ If the committee refuses to give its approval, it must state its reasons for so doing. The process of decision-making in the committee meetings is, however, subject to the rules of confidentiality.

6.2.3. COMPOSITION

Whereas the role of the committee is clearly designated, the AMG does not stipulate what its composition should be, an issue which has been the subject of controversy. The German Medical Association drew up guidelines concerning the composition of *Ethik-Kommissionen* in 1979. They provided that *Ethik-Kommissionen* should include at least four doctors, one of whom would be designated as the chairman. However, in direct contrast, to both the Department of Health (DoH) guidelines and those issued by the

³³§ 40 (1) Nr 7a AMG and further Laufs A, fn 20 above at pp. 20-21.

³⁴See Tierschutzgesetz of 18. 8. 1986 I, BGBl. 1319 and also Gen Technikgesetz of 20. 6. 1990 I, BGBl. 1080.

³⁵This is a clear implementation of the EC Good Clinical Practice Guidelines which provide that, "The Ethics Committee should be asked to give its opinion and advice in writing." 1.5 Good Clinical Practice for trials on medicinal products in the European Community. See Notes for Guidance on Good Clinical Practice for Trials on Medicinal Products in The European Community (EC) 1990 III / 3976 / 88 - EN. [Approved July 1990; effective July 1991]. Also published in Pharmacology & Toxicology (1990) 67 at pp. 361-372.

Royal College of Physicians in the United Kingdom, the role of committee members is precisely defined, leaving little room for discretion. Two of the medical practitioners must be in clinical practice and at least one must be an experienced researcher. The doctors are entrusted to advise on the medical viability of the proposal. The guidelines further provide that a lawyer should be among the members of the committee whose role it is to advise on the legal implications of a research proposal. The principle is that doctors must rely on the lawyer's opinion concerning the legal aspects of the proposal.³⁶ Each member should serve a term of four years.³⁷ As in the United Kingdom, the composition of committees is inherently professional.

In 1985, the BÄK set up a working party whose remit was to update the 1979 guidelines. It concluded that *Ethik-Kommissionen* ought to include scientists as well as doctors. It further stipulated that additional membership ought to include at least one or more lay people together with one lawyer. Moreover, the proportion of men and women ought to be as near equal as possible. There are as yet no provisions for patient representatives to sit on committees despite the fact that substantial opinion favours such a provision.³⁸ It was proposed that the total number of members of the committee should range between seven and nine.

6.2.4. *ETHIK-KOMMISSIONEN* IN PRACTICE

Research has shown that the practices of *Ethik-Kommissionen* differ widely. Moreover, like their British counterparts, *Ethik-Kommissionen* have experienced a rise in the number of research proposals they are being asked to consider.³⁹ Sixty five meetings of the *Ethik-Kommission* were held at the University clinic in Hannover between 1984-1993; 1260 proposals were reviewed which amounts to approximately 19 per sitting. Amendments had to be made in 422 cases (approximately 6 per meeting). Six proposals

³⁶However, the lawyer will vote on the medical merits of the proposal.

³⁷See Bork, R *Das Verfahren vor den Ethik-Kommissionen der medizinischen Fachbereiche* (1984) at 168 for commentary.

³⁸See *Der Tagesspiegel* June 25, 1995 at p. 9.

³⁹Pichlmayer et al, fn 15 above at 35.

were refused outright. A third of proposals were sent back to the researchers for amendment.

The results of empirical research undertaken by Joachim Czwalinna⁴⁰ were published in 1986. This concentrated on the composition and the practices of *Ethik-Kommissionen* and was comparable to the Neuberger Report in the United Kingdom.⁴¹ The findings can be summarised;

1.

The number of members of *Ethik-Kommissionen* usually varied between three to nineteen members of which five to seven are actively involved. Most of the members were medical professionals, some of whom were trained as pharmacologists whilst others had purely academic roles. Nursing staff and medical students were very rarely included.⁴² The committees seldom had statisticians amongst their members, despite their possible input as regards the assessment of biomedical factors, the most important of which lay in the risk / benefit equation.⁴³

Czwalinna maintained that the doctors should not be selected from the same institution in which the research is being carried out. This, he pointed out, avoids the possibility of the medical members of the committee reviewing the work of their colleagues and more importantly, the possibility of the doctors being influenced by the need to enhance the research reputation of the institution.⁴⁴

2.

Two thirds of the committees had a lawyer among their members who was usually an academic with the occasional judge and a member of a university's legal advisory service.⁴⁵

⁴⁰Czwalinna, J 'Ethik-Kommissionen für die medizinischer Forschung am Menschen-Bestand, Struktur und Vorgehensweise' MedR 86, 305.

⁴¹Neuberger, J *Ethics and Healthcare; The Role of Research Ethics Committees in the United Kingdom* (1992).

⁴²In Continental Europe, medical students must fulfill certain tasks as part of their vocational training of which membership of a REC could be a part. This would not apply in the United Kingdom.

⁴³See Deutsch at fn 21 above at 306.

⁴⁴This is also a relevant consideration in the United Kingdom, especially as regards research carried out at universities, where, in view of the continuous bidding for funding, they are having to compete to attract greater public spending.

⁴⁵The lawyer's position in 1985 was the same as it is in the United Kingdom at the present time to the extent that lawyers are not there as of right. This is also a relevant consideration in the United Kingdom, especially as regards research carried out at universities, where, in view of the continuous bid for funding, they are having to compete to attract greater public spending. Note that Czwalinna's research predated the 1985 recommendations. (April 1984 - October 1985).

Czwalinna accepted that this might have something to do with the role of *Ethik-Kommissionen* in that they are advisory and not, what he refers to as, supervisory bodies. However, he refuted this by arguing that these committees are entrusted with assessing the moral *and* the legal viability of research projects. Hence, a lawyer with the necessary background in medical negligence ought to sit on a committee as of right.⁴⁶

3.

Seven out of the thirty-three committees examined had a theologian and/or a philosopher as a member.⁴⁷ Czwalinna pointed out that it is doubtful whether people trained at such a high theoretical level could be effective in view of the practical discipline required of committee members. He further pointed out that the development of 'Bioethicists' in the United States has not been followed in Germany. However, the potential input of such members in relation to specific questions, for example, embryo research, would be advisable. It was not considered whether such members ought to be full time committee members.⁴⁸

Czwalinna's results indicate that *Ethik-Kommissionen* are strongly influenced by the professional élite. As in the United Kingdom, for example, lay members are selected with reference to professional benchmarks; this can occur because neither the AMG or the BÄK guidelines specify how members should be chosen.

As further examples, the research ethics committee at the University clinic Rudolf Virchow in Berlin includes seven medical professionals.⁴⁹ The other ten members are lay members and are from the legal profession, theology, psychology, mathematics and biology. Patient and student representatives also sit on the committee.⁵⁰ Members of the committee at the Max Delbrück centre in Buch, include a nurse and a theologian as well as six professors from the disciplines of law, molecular biology and medicine.

⁴⁶See Czwalinna, fn 40 above at 307. The insistence on negligence emphasizes the concern for the legal position of the committee and the for the researcher.

⁴⁷See Czwalinna, fn 40 above at 307.

⁴⁸I believe that such members should be co-opted. This is discussed in further depth in the chapter dealing with research ethics committees in the United Kingdom.

⁴⁹Trained in paediatrics, psychiatry, anaesthesia and pharmacology.

⁵⁰See *Der Tagesspiegel* May 29, 1995 at p. 21.

The members of the *Ethik-kommission* in Hannover included a surgeon, an internist, a pharmacologist, an expert in legal medicine (*Rechtsmediziner*), a statistician, a retired doctor and a lawyer. There were no patient representatives although this is currently under review.⁵¹

The rules in relation to composition of *Ethik-Kommissionen* for research involving human subjects leave a lot to be desired. Indeed, it might well be argued that the framers of the AMG should have included provisions relating to composition when they amended the code in 1994. The codes governing biotechnology and the protection of animals go into far greater detail regarding the composition of these supervisory committees. There is no limit as to who may participate in the decision-making process; no categories of person are excluded from membership.

6.2.1. SPECIALISED ETHICS COMMITTEES - THE GENTECHNIKGESETZ AND THE TIERSCHUTZGESETZ

The statute regulating biotechnology (*Gentechnikgesetz (GenT)*) 1990 applies to all genetic engineering other than that relating to human embryos. It was introduced at the same time as the statute regulating embryology although it is not as strict as the latter. The *Gentechnikgesetz* represents the middle road and was introduced as a way of ensuring that Germany does not fall behind in matters of research and development.⁵² Very much in the way of the AMG, the statute arose through the pressure of industry.⁵³ The emphasis of the Act provides a legal framework for genetic research. For example, section 1 states that,

⁵¹Pichlmayer and Nagel, fn 15 above at 35-36.

⁵²See Riedel, E 'The Constitution and Scientific and Technical Progress' in Starck, R (ed) *New Challenges to the German Basic Law* (1991) at 68.

⁵³This has been referred to as the 'brain drain' of researchers who leave Germany in order to conduct research in countries which allows research which is banned in Germany to be undertaken. See Riedel, fn 52 above at 68 and also Hügel H, Fischer J, Kohm, B *Pharmazeutische Gesetzeskunde* (28th edn, 1990) at 175. Note that the *Gentechnikgesetz* implemented an EC directive 90/219 on the contained use of genetically modified micro-organisms. This directive was implemented in the United Kingdom through SI 1992/3217 The Genetically Modified Organisms (Contained Use) Regulations 1992 and SI 1996/967 The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996.

It is the purpose of the Act

1. to protect life and wealth of human beings, animals, plants and commodities as well as the entire environment in its interrelationships (*die Umwelt in ihrem Wirkungsgefüge*) from possible dangers emanating from gene technology, procedures and products, and to prevent the occurrence of such dangers;
2. to create the legal framework for research, development and utilization of scientific and technical possibilities (potentials) of gene technology.⁵⁴

All genetic engineering is thereby placed under the aegis of preventive state control. The statute creates a licensing authority which deals with the registration of licensing applications and which must decide whether an intended project is free from dangers to human beings and to the environment.⁵⁵

Provisions regarding the composition of genetic research committees go into considerable detail.⁵⁶ The committee is made up of experts which should include, *inter alia*, experts in microbiology, cellular biology, virology, genetics and ecology as well as representatives from unions, industry and environmental and research organisations.⁵⁷ The *Gentechnikgesetz* emphasises the need to involve representatives from the public and also provides for public hearings which may not exceed a period of three months.⁵⁸ As regards its role, the committee, must test and judge issues of biotechnology with the aim of advising the government and the regions. Moreover, the committee must publish a yearly report as a summary of its practices.

The sanctions which the statute imposes are relatively mild compared to those laid down by the code governing the protection of embryos (*Embryonenschutzgesetz*) which provides, for example, that any artificial alteration of genetic information of a human

⁵⁴Translation by Riedel, fn 52 above at 68.

⁵⁵See §§ 7-13 and 14-16 of the GenT of 20. 6. 1990 I, BGBl. 1080.

⁵⁶See §§ 4 and 5 of the GenT, fn 55 above at 1082.

⁵⁷§ 4 (1) Nr. 1 and 2 GenT, fn 55 above.

⁵⁸In the event of deliberate release of genetically modified organisms into the environment, a prior assessment must be made by a Federal Gene Technology Commission (*Zentrale Kommission für Biologische Sicherheit - ZKBS*). See §§ 4, 5 GenT, fn 55 above at 1080.

germinal cell will be punishable by up to five years' imprisonment.⁵⁹ By contrast, the *Gentechnikgesetz* invokes criminal liability only in the event of breaches of duty have led to the endangerment of life or health of human beings.⁶⁰ Otherwise, it imposes administrative summary fines (*Bußgeld*) or in some instances criminal fines.⁶¹ The difference in style of the legislation is well summarised;

"To speak simply of legal prohibitions would be misleading, for a legal order can function primarily to facilitate (as in the law of contracts or wills) rather than to limit (as in the law of crimes). Of course, it is a matter of emphasis: To facilitate requires rules of order, and to impose controls will serve to facilitate; but the difference in priorities is significant for the choice, or the admixture of legal patterns of order. Two such patterns seem particularly relevant to medical experimentation with human beings. One is the model of the voluntary association or community. The other is the imposition of extrinsic standards and sanctions for their break."⁶²

The same precision as regards composition of committees applies to the code regulating research including animals (*Tierschutzgesetz*) which provides that a third of committee members must be vets, medical professionals or those with a background in the natural sciences. It is of interest to note that the provisions also include the right for lobbying groups to be included; members of the committee should also be selected from societies for the protection of animals.⁶³

⁵⁹§ 5 Embryonenschutzgesetz (ESchG) of 13. 12. 1990 I, BGBl. 2746. Imprisonment of up to three years or the imposition of fines may ensue where, for example, an unfertilised ovum has been transplanted or in the event of artificial insemination of an ovum for other purposes than to bring about pregnancy of the woman from whom the ovum stems. See § 1. For a general summary of the German position see Goldbeck-Wood, S 'Europe is divided on embryo regulations' (1996) 313 BMJ 512.

⁶⁰And to significant commodities or to natural resources of ecological importance.

⁶¹See §§ 38 and 39 of the GenT, fn 55 above at 1082.

⁶²See Freund in Daedalus 98 (1969) at 315 et seq cited in Deutsch, E *Das Recht der Klinischen Forschung am Menschen* (1979) at 35.

⁶³§ 15 (1) Nr. 2. Tierschutzgesetz 1986 I, BGBl. 1319 which provides that, "Die Mehrheit der Kommissionsmitglieder muß die für die Beurteilung von Tierversuchen erforderlichen Fachkenntnisse der Veterinärmedizin, der Medizin oder einer naturwissenschaftlichen Fachrichtung haben. In die Kommission sind auch Mitglieder zu berufen, die aus Vorschlagslisten der Tierschutzorganisationen ausgewählt worden sind und auf Grund ihrer Erfahrung zur Beurteilung von Tierschutzfragen geeignet sind; die Zahl dieser Mitglieder muß ein Drittel der kommissionsmitglieder betragen.", or, "The majority of the committee's members entrusted to supervise animal experiments must have the requisite professional knowledge of veterinary science, medicine or the natural sciences. Members of the committee must also be selected from lists put forward by animal welfare groups; these members must account for a third of the total committee's membership."

Ethik-Kommissionen are not as strictly regulated as are those concerned with animals and embryos which is why the amendment to the AMG has been referred to as “soft law”.⁶⁴ In particular, the amendment of the AMG does not go far enough in relation to the composition of committees entrusted to supervise genetic and animal research. The rationale upon which both committees are based is inherently inclusive. However, the procedures according to which the committees established by the *Tierschutzgesetz* and the *Embryonenschutzgesetz* operate is prescribed; there is little room for disunity as regards practices. Hence, there is little likelihood of “forum shopping” between different regions within Germany. To this extent, the legal framework provided by both the *Gentechnikgesetz* and the *Tierschutzgesetz* has much to offer as regards the regulation of medical research involving human subjects in both Germany and the United Kingdom.

6.3. ACCOUNTABILITY OF ETHIK KOMMISSIONEN

Questions as to accountability have also been raised in relation to research ethics committees in Germany, with an emphasis on the overall lack of transparency.⁶⁵ It is commonly felt that they practice behind closed doors.⁶⁶ Legal accountability of research ethics committees in Germany is centred on fault. Liability towards research subjects, for example, may be contractual, delictual and in some cases even criminal.⁶⁷

The institution responsible for setting up the committee exercises a supervisory role. Control may be administered at a primary level by the president or the minister of a medical faculty or by the department (*Ministerium*) of an *Ärztchammer*. These supervisory bodies may annul a decision of an *Ethik-Kommission* or they may advise the committee to reach a decision. However, they are not allowed to consider the validity of a research proposal.

⁶⁴See Sobota, fn 3 above at 234.

⁶⁵See *Der Tagesspiegel* May, 29, 1995 at p. 21.

⁶⁶Losse, H ‘Aufgaben und Probleme medizinischer Ethikkommissionen’ in Schlaudraff, U (ed) *Ethik in der Medizin* (1987) at p. 13.

⁶⁷Criminal liability is discussed below.

Whereas the position in the United Kingdom is that legal accountability is provided by redress to the administrative law remedy of judicial review and by the tort of negligence, in Germany, legal accountability of *Ethik-Kommissionen* is ensured by further recourse to remedies contained in the civil and the criminal law.⁶⁸ Each will be examined.

6.3.1. ADMINISTRATIVE LAW (*VERWALTUNGSRECHT*)

Historically speaking, German administrative law was influenced by the French legal tradition of placing a strong emphasis on the legal control of administrative decisions. Gradually, this emphasis shifted to the protection of individual rights through recourse to the courts.⁶⁹ The historical development of administrative law in the United Kingdom was markedly different in view of the reluctance to accept it as a subject in its own right.⁷⁰ Both systems however, share a common theme which underlies the concept of administrative law namely, the legal control of governmental powers.⁷¹ At a fundamental level, administrative law regulates the relationship between the administration and the citizen.⁷²

In order for a challenge of the decision taken by an *Ethik-Kommission* to be allowed, it must be shown that the decision amounts to an administrative act which has been defined as,

⁶⁸In the United States, IRBs have already been charged by research subjects. 'The Tort Liability of Hospital Ethics Committees' (1987) 60 Southern California Law Rev 1239.

⁶⁹See p. xiii of the introduction by Conrad, D in Singh, M P *German Administrative Law* (1985).

⁷⁰Notably due to the views of the British constitutional lawyer A V Dicey in his book *Introduction to the Study of the Law of the Constitution* (10th edn, 1959) at p. 183 et seq. and also at p. 330 who, in analysing the French legal system, came to the conclusion that it was not advisable to transpose the concept of *droit administratif* into the English legal system. However, despite his later revocation of this view, which is reproduced in the above mentioned work at p. 493, it has since been noted that this conclusion was based on a misinterpretation of the status of the Rule of Law in the French legal framework which he equated with the all-comprehensive jurisdiction of ordinary courts and the absence of any specific body of administrative law. See Singh, fn 69 above at ix.

⁷¹Singh, fn 69 above at 1.

⁷²Singh, fn 69 above at 2.

“every order, decision or other sovereign measure taken by an authority for the regulation of a particular case in the sphere of public law and directed at immediate external legal consequences.”⁷³

‘Sovereignty’ refers to measures which are only sovereign if they pertain to public law.⁷⁴ Hence, the act must come under the heading of administrative law.⁷⁵

Ethik-Kommissionen are not public bodies *per se*, but their practices must meet the standards which are applied to public bodies.⁷⁶ Hence, like his counterpart in the United Kingdom, a researcher seeking a remedy against the decision of an *Ethik-Kommission* could rely on administrative law by applying for judicial review. According to principles of German administrative law, an individual may seek a remedy by judicial review in the administrative courts if he is of the opinion that his rights have been breached.

6.3.1.1. JUDICIAL REVIEW

The protection of individual rights lies at the heart of the Basic Law. According to article 19 (4) GG, recourse to the courts is guaranteed where basic rights have been violated by a public authority.⁷⁷ It provides that,

“Where rights are violated by public authority the person affected shall have recourse to law. In so far as no other jurisdiction has been established such recourse shall be to the ordinary courts.”⁷⁸

⁷³See the Law of Administrative Procedure (*Verwaltungsverfahrensgesetz*) May 25, 1976 § 35, 1976 BGBl. I 1253, 1263 and more recently cited by Tyler T J ‘Legal Update’ (1994) 29 Texas International Law Journal 467 at p. 500.

⁷⁴For this section see Tyler, fn 73 above at 500.

⁷⁵An authority is public if it performs public functions which includes administering institutions and public authorities. A regulation is an act which creates legal consequences which must satisfy the direct legal effects test; the act must create legal effects on the individual which are immediate as opposed to attenuated. Finally, the phrase ‘particular case’ relies on the distinction between administrative acts and legislative acts. An act is regarded as being administrative if it seeks to govern a definite numbers of persons and in relation to definite facts as opposed to a legislative act which is general in nature.

⁷⁶Deutsch fn 28 above at 432.

⁷⁷See generally Starck, C *Praxis der Verfassungsauslegung: Studien und Materialien zur Verfassungsgerichtsbarkeit* (1994) at 16 and also Von Münch, I / Kunig, P *Grundgesetz-Kommentar* (4th edn, 1992) Rn. 48 zu Art. 19 (4) GG.

⁷⁸Article 19 (4) of the Basic Law. See *The Basic Law for the Federal Republic of Germany* (Translation by the Press and Information Office of the Federal Government Bonn 1994).

The state is thereby obliged to provide an institutional guarantee of jurisdiction (*Gerichtsbareit*), ensuring that rights of individuals are safeguarded as against emanations of the state.⁷⁹ The Basic Law thereby ensures the protection of individual rights, referred to as the *subjektives Recht* which is founded on the notion of personal interest.⁸⁰ Article 19 (4)'s remit is wide to the extent that it protects the whole sphere of the individual dealings with the state.⁸¹ It serves both individual protection and administrative control.⁸²

A direct application for judicial review is available only to a plaintiff who alleges the violation of a legally protected right.⁸³ Essentially, the right must derive from a rule of law or statute which typifies the individual's interest. The legality of a decision can be challenged on grounds of competence, procedure and substance.⁸⁴

In contrast to the position in the United Kingdom, Germany has separate administrative courts which exercise a broad jurisdiction.⁸⁵ These courts deal with purely public matters and, in particular, consider disputes between the public authorities and individuals resulting from the actions of those in authority.⁸⁶ A researcher could make an application for judicial review by virtue of his subjective right (*subjektives Recht*). He

⁷⁹See Von Münch / Kunig, fn 77 above at Rn. 49 zu Art. 19 (4) GG and also Dürig, G in Gläeser, W S and Häberle, P (eds) *Gesammelte Schriften 1952-1983* (1984) at p. 198.

⁸⁰The legal doctrines of *Abwehr* and *Leistung* which exist in the Basic Law are defined as follows. *Abwehr* refers to those acts which are prohibited. *Leistung* however, refers to what may be literally translated as performance. Hence, it provides a special right which an individual may invoke if he wishes the court to determine whether he may be allowed to engage in certain behaviour. See Von Münch / Kunig, fn 77 above at Rn. 47 and 59 and also Starck, fn 77 above at 46-47.

⁸¹Dürig and Gläeser, fn 79 above at 198.

⁸²Dürig and Gläeser, fn 79 above at 203. And also Hesse, K *Grundzüge des Verfassungsrecht der Bundesrepublik Deutschland* (18th edn, 1991) at § 6 at p. 83.

⁸³§ 42 VwGO. See Maunz, T and Zippelius, R *Deutsches Staatsrecht* (28th edn, 1991) at § 21 I at p. 167.

⁸⁴§ 44 VwVfG. Nigel Foster provides a concise outline of the rules of procedure in his book *German Law and Legal System* (1993) at p. 133.

⁸⁵Although see de Smith, S A *Judicial Review of Administrative Action* (4th edn, 1980) at p. 3 and in particular for a brief discussion on the Scotland Bill and the attempt to establish a Constitutional Council which would be entrusted of reviewing the legality of assembly measures.

⁸⁶The procedure of the courts is regulated by the rules of procedure (*Verwaltungsgerichtsordnung: VwGO*).

would do this by recourse to the procedural rules as contained in the Administrative Courts Act (§ 40 VwGO) alleging that the method in which the *Ethik-Kommission* reached its decision was unreasonable.

The nature of the claim would be that of a *Leistungs-Klage*⁸⁷ and would only be admissible if the individual could produce a *prima facie* case that his rights had been breached.⁸⁸ He would need to show that he had sufficient interest in the outcome of the deliberations of the committee.⁸⁹ The outcome of the *Leistungs-Klage* is to bring about a new consideration of the case. This gives a committee considerable leeway insofar as a challenge could only be brought if the grounds were sufficiently serious.⁹⁰

6.3.1.2. THE EFFECTIVENESS OF A REMEDY UNDER ADMINISTRATIVE LAW

There are no recorded instances where the decision of an *Ethik-Kommission* has been challenged. Thus, we can only hypothesise as to its effectiveness as a method of defining the accountability of research ethics committees. Consideration of the general criticisms have been raised in relation to judicial review; these may provide us with an insight into the particular conditions under review.

It has been argued that Art. 19 (4) is not only a formal right or a theoretical possibility of involving the administrative courts, but also aims to ensure the effective protection of rights so that an individual may be able to bring the control mechanism into force.⁹¹ Effectiveness is a relative concept but has been interpreted as being constituted of the principles of workability, worth and enforceability.⁹² All of these can be questioned in respect of judicial review to the extent that it is not a realistic option in view of the high costs of bringing an action and the inherent delays involved.⁹³

⁸⁷Roughly interference with an inherent right. See Deutsch, fn 21 above at 432.

⁸⁸See § 2 VwGO.

⁸⁹§ 43 (1).

⁹⁰Deutsch, fn 21 above at 309.

⁹¹See Lorenz, D 'Das Gebot effektiven Rechtsschutzes des Art. 19 Abs 4 GG' Jura 1983 at 393.

⁹²Lorenz, fn 91 above at 394.

⁹³Stein, E *Staatsrecht* (14th edn, 1993) § 53 II at p. 429.

6.3.2. CIVIL LAW: § 839 OF THE CIVIL CODE (BGB)

A duty of care owed by the *Ethik-Kommissionen* derives from the liability of the State as provided in the Basic Law (Art 34 GG):

“If any person, in the exercise of a public office entrusted to him, violates his official obligations to a third party, liability shall rest in principle on the state or the public body which employs him. In the event of wilful intent or gross negligence the right of recourse shall be reserved. In respect of the claim for compensation or the right of recourse, the jurisdiction of the ordinary courts must not be excluded.”

However, the claim which may be brought under this section is a private claim and can be brought under § 839 of the Civil Code (BGB) which provides that,

(1) If an official wilfully or negligently commits a breach of official duty incumbent upon him towards a third party, he shall compensate the third party for any damage arising therefrom. If only negligence is imputable to the official, he may be held liable only if the injured party is unable to obtain compensation.[sic].

(2) If an official commits a breach of his official duty in giving judgment in an action, he is not responsible for any damage arising therefrom, unless the breach of duty is subject to a public penalty to be enforced by criminal proceedings. This provision does not apply to a breach of duty consisting of refusal or delay in the exercise of the office.

(3) The duty to make compensation does not arise if the injured party has wilfully or negligently omitted to avert the injury by making use of a legal remedy.⁹⁴

In essence, the paragraph upholds the personal liability of a state official which may be invoked for any damage arising from the unlawful conduct on his part. Much, however, depends on the nature of the act of an official as he may be exercising a sovereign act (*iure imperii*) or he may be exercising an act which is contained in private law on behalf of the state.⁹⁵

⁹⁴Translation by Forrester, I S and Ilgen, H M *The German Civil Code* in Markesinis, B S *An Introduction to the German Law of Torts* (3rd edn, 1994) at 12.

⁹⁵This is particularly relevant where pharmaceutical companies are the sponsors of a research project. The distinction illustrating the public / private divide must be questioned in view of the increasingly active role of the State in the market place.

The essence of the claim is that it is pursued before the civil courts despite its public law nature. Administrative courts do not have jurisdiction if a civil claim can be brought. The duty of care is based on liability for omissions which is based on the idea that a potential or preceeding danger gives rise to a duty of care. This duty, which was developed by the German courts, is referred as *Verkehrssicherung*; if a person creates a source of potential danger which is likely to affect the interests and rights of others, he is obliged both to ensure and insure their protection against the risks which he has created.⁹⁶

In the event of the committee having negligently approved a proposal from which harm ensued, liability may be invoked not only against the committee itself but also against any supervisory body.⁹⁷

6.3.2.1.(A). THE SUPERVISORY BODY

Whoever is responsible for the establishment of an *Ethik-Kommission* takes on the role of a supervisory body. This supervisory body is in breach of its duty of care if it fails to set up an *Ethik-Kommission*, if it fails to organise it in a proper manner or if it fails to maintain an effective degree of supervision. A researcher may bring an action against an *Ethik-Kommission* in the civil courts on the basis of the rejection of his proposal or if he is of the opinion that the proposal was not scrutinised in a fair manner or where the committee delayed in giving a response. The legal basis of bringing such an action is to be found in Article 5 (3) of the basic law which upholds a researcher's subjective right to research freedom; this is a personal right which is established by his interest in the research proposal.⁹⁸

⁹⁶Markesinis, fn 94 above at 75 .

⁹⁷See further.

⁹⁸Article 5 (3) GG provides that "Art and scholarship, research and teaching shall be free. Freedom of teaching shall not absolve anybody from loyalty to the constitution." See The Basic Law, fn 78 above and also Chapter One. Free in this context relates both to academic freedom and freedom from financial constraints.

6.3.2.1.(B). THE *ETHIK-KOMMISSION*

A committee will be liable if it negligently approves a trial which results in harm to the research subjects. Doctors would also incur liability in view of their position as state officials.⁹⁹ The Basic Law provides the legal basis for the proposition that individual members of an *Ethik-Kommission* may be held personally liable in an action in negligence.

In practice, a plaintiff would seek to bring an action against the state body rather than the individual physician or the *Ethik-Kommission*.¹⁰⁰ There is nothing to suggest, however, that it would be impossible to bring an action against the committee itself or even against individual members¹⁰¹ - it is simply that it would be less likely to succeed.

The basis of a civil claim rests on the allegation of serious misconduct. The remedies sought would be limited to compensation (*Geldersatz*) which is awarded on the basis of 'natural restitution' for the damage which ensued.¹⁰² However, the burden of proof which would need to be discharged is sufficiently stringent to raise doubts as to whether such a claim would ever succeed against a committee. Indeed, this is the reason why such claims are seldom brought - and in fact would appear to have never been brought. This argument, however, seriously reduces the strength of civil action as a way of enforcing accountability.

⁹⁹§ 839 BGB Art 34 GG See also Giesen, D *Civil Liability of physicians with regard to new methods of treatment and experiments* (1976) p. 48.

¹⁰⁰Even though a supervisory body could raise the issue of the liability of both a doctor and an *Ethik-Kommission*.

¹⁰¹Deutsch, fn 28 above at 432.

¹⁰²Palandt, O *Bürgerliches Gesetzbuch*, (54 edn, 1995) at 989.

6.3.2.1.2. § 823 (1) of the Civil Code (BGB).

An action could be brought under the Civil Code by the sponsors of a research project (*Auftraggebers*) against the committee for an infringement of their right to commercial enterprise (*Gewerbebetrieb*) which is laid down by § 823 Abs. 1 BGB which protects against commercial interference.¹⁰³ This is a protective law (*Schutzgesetz*) which has been described¹⁰⁴ as being so narrow that the paragraph only applies where specific stated interests have been violated.¹⁰⁵ However, the requirements of the paragraph are also fairly wide in that it covers intention as well as negligence. Early cases brought under the paragraph concerned conduct which hindered the business activities of a competing enterprise. Hence, the right could only be invoked by businesses or commercial enterprises. Decisions related to trials sponsored by drug companies under the auspices of the public *Ethik-Kommissionen* or by companies whose trials are approved by free *Ethik-Kommissionen* would obviously come under this heading.

The clause is the product of continuous judicial activity which has emphasized that the right be kept within reasonable bounds.¹⁰⁶ Accordingly, the interference with the business interests must be 'direct' before it can become actionable. The test adopted by the Supreme Court seeks to determine whether the conduct of the defendant will constitute an invasion of the plaintiff's right if it is 'business connected' i.e. "...in some way directed against the business as such...and must not simply affect rights and interests which are separable from the business as a functioning unit".

¹⁰³"A Person who wilfully or negligently injures the life, body, health, freedom, property, or other right of another contrary to law is bound to compensate him for any damage arising therefrom.

The same obligation attaches to a person who infringes a statutory provision intended for the protection of others. If according to the purview of the statute infringement is possible even without fault, the duty to make compensation arises only if some fault can be imputed to the wrongdoer." § 823 BGB. See Forrester and Ilgen, in Markesinis, fn 94 above at 12.

¹⁰⁴Markesinis, fn 94 above at 35 et seq.

¹⁰⁵These would include life and bodily health. There must be a causal link between the defendant's conduct (act or omission) and the plaintiff's harm as defined by this paragraph. The kind of harm which is not protected is economic loss unless it is the result of physical damage. Economic loss claims are usually brought under § 826 BGB.

¹⁰⁶See Deutsch E JZ 1984, 308.

6.3.2.2. Criminal Law: § 226 a St Gb

Discussion of the role of criminal law in relation to accountability of research ethics committees is justified in view of the criminal sanctions which the AMG provides.¹⁰⁷ It is difficult to conceive of any *Ethik-Kommission* offending in a manifestly criminal way although criminal recklessness might be inferred were a dangerous proposal passed with an inexcusable lack of consideration and harm ensued.¹⁰⁸ A less unlikely application of the Criminal Code to the work of research ethics committees is to be found in the concept of consent. Put at its simplest, consent to a 'touching' elides the prospect of an action for assault; it is at least possible that a *Kommission* which authorised research to which the subjects had not consented would be as subject to criminal - and indeed to civil - sanctions as would the researchers themselves.

A more specific and interesting consideration lies in the legality of consent to risk. Bearing in mind that consent to severe injury is invalid, can it be that consent to risk which might result in severe injury is equally invalid? And to what extent would a *Kommission* that approved such a dangerous project be responsible for any resultant damage?¹⁰⁹ Paragraph 226 of the German Criminal Code (StGB) provides that consent to being harmed is invalid if it contravenes public policy (*guten Sitten*).¹¹⁰ Criminality and public policy are, therefore, intimately bound in this context and it may be that the latter is the more important in enforcing accountability of *Kommissionen*.

¹⁰⁷ § 38 AMG. See Chapter One at Section 1.7.4.3.

¹⁰⁸ Recklessness in relation to bodily harm (*Fahrlässigkeit*) is dealt with in § 230 of the Criminal Code.

¹⁰⁹ "...there may be those who would accept risks of a very high order for admirable altruistic reasons and it is questionable whether they should be prevented from so doing. There are legal limits to the extent to which consent decriminalises the infliction of harm and it is interesting to speculate whether the consent of a volunteer to a dangerous medical experiment would serve as a defence to a charge of assault or homicide." See Mason, J K and McCall-Smith, R A *Law and Medical Ethics* (4th edn, 1994) at 352 where they cite *A-G's Reference (No 6 of 1980)* [1981] QB 715, [1981] 2 All ER 1057, CA; *Smart v. HM Advocate* 1975 SLT 65 as authorities. See also Williams, G 'Consent and Public Policy' [1962] Crim LR 74, 154.

¹¹⁰ See § 226a St GB which provides that, "Einwilligung des Verletzten. Wer eine Körperverletzung mit Einwilligung des Verletzten vornimmt, handelt nur dann rechtswidrig, wenn die Tat trotz der Einwilligung gegen die guten Sitten verstößt." Which translates as: "Consent of the Injured Person. He who injures an individual with his consent is liable only if the act is contrary to public policy". See § 96 Nr. 10 AMG i. V. m. and § 40, 41 AMG.

6.3.2.3. PUBLIC POLICY (*GUTE SITTEN*); A LEGAL OVERVIEW

The concept of *gute Sitten* derives from the Roman law principle of *contra bonos mores* which was traditionally applied to contracts which were held to be invalid if they contravened public morality.¹¹¹ The German courts developed the concept of *Rechtsmoral* which is a way of adapting the law to encompass moral considerations. The concept is founded on the distinction between *Sitte*, *Moral* und *Recht*, with *Sitten* providing concrete principles on which to base the law.¹¹² As with its common law counterpart, the difficulty with this concept is that it is vague and it is consequently difficult to lay down precise guidelines.¹¹³

It is generally held that if an act contravenes the common principles of justice and decency, it goes against public policy. The question to be decided is whether and to what extent the decency of the act can be isolated from its purpose; this involves an exercise in the balance of interests (*Interessenabwägung*) which provides that if an individual is following a positive purpose - an example of which is obtaining organs from living donors for transplantation - the balance of interests will tip in his favour. Thus, the decisive factor is the extent of the danger to bodily harm in relation to its purpose. The greater the danger and the lesser the value / merit which accompanies this purpose, the more likely the act will contravene public policy.

¹¹¹This contractual principle is still to be found in the German Civil Code. See § 138 (1) BGB.

¹¹²Singh, fn 69 above at 3-6. Although it has been questioned whether these concepts can be distinguished quite so clearly. The word *Sitte* ordinarily refers to custom or usage but in its legal sense, can be translated as public morality or policy. Indeed, public policy is the common law equivalent to *guten Sitten*. See Dietl, *C-E Dictionary of Legal, Commercial and Political Terms* (1983) and also Simitis, *K. Gute Sitten und Ordre Public* (1960) at 112.

¹¹³Indeed, it has been argued that the '*gute Sitten*' concept as contained in § 226a may not be in accordance with Art. 103 (2) of the Basic Law due to its lack of legal clarity and certainty. A particular example would relate to sterilisation procedures carried out for social reasons. See Breithaupt, *JZ* 1964 283.

6.3.2.3.1. Consent

It follows that, despite consent having been obtained, the researcher incurs the possibility of being held criminally liable in the event of the research subject suffering serious harm during the course of an experiment which is particularly dangerous or reprehensible.¹¹⁴ Going one step further, can one justifiably maintain that the researchers' responsibility is discharged once the subjects have been informed of, and fully understand, the risks when they consent? The concept of *gute Sitten* is the deciding factor in this respect.

Under paragraph 226a, consent to injury is valid unless it contravenes morality. This applies to all forms of bodily harm and includes reckless bodily harm.¹¹⁵ Furthermore, paragraph 226a applies to bodily harm once it has occurred and also to possible bodily harm. In the case *Celle* MDR 69, 69, it was held that consent must be based on a clear understanding of the risks involved.¹¹⁶ Thus, an individual must comprehend the extent of the risks but engage in the act nevertheless.

It is likely that in Germany, in view of its strict controls on human experimentation, a case of unethical research would satisfy the criteria of social unacceptability (*Sozialethisches Unwerturteil*) which is an element in the concept of *gute Sitten*. This is based on the examples of *Sittenwidrigkeit* which include injuries sustained through sadomasochistic injuries which are so serious as to involve danger to the body or the life of an individual. It is suggested that injuries sustained during the course of medical research which does not have a recognised purpose (*anerkannter Zweck*) is an example of *Sittenwidrigkeit*.

¹¹⁴The practical implications of this principle as regards medical interventions has come up under procedures for sterilisation and castration procedures.

See Schönke / Schröder, *Strafgesetzbuch* (1995), Rn. 14.

¹¹⁵*Rut NJW* 63 165.

¹¹⁶*Celle* MDR 69 at 70.

6.3.2.5. BODILY HARM TO THE INDIVIDUAL (§223 StGB : KÖRPERVERLETZUNG)

Paragraph 226a is founded on the provisions in the Criminal Code relating to harm to the individual. Paragraph 223 StGB aims to protect the bodily integrity and the health of the individual. The law distinguishes between bodily harm and injury to health; these two forms may coexist but they are independent of each other. Possible forms of injury include those suffered by research subjects during the course of human research.¹¹⁷ The harm which ensues may be defined as grievous bodily harm (*schwere Körperverletzungen*)¹¹⁸ and actual bodily harm (*leichte Körperverletzungen*).¹¹⁹ The importance of maintaining the distinction lies in the possible sentences which may be imposed under each paragraph.

6.4. PROPOSALS FOR REFORM

6.4.1. A CASE FOR A NATIONAL ETHICS COMMITTEE ?

As in the United Kingdom, arguments have been raised in favour of a national committee responsible for investigating the wider implications of public interest issues - such as the allocation of resources in research, and gender issues - for example, the possibility of including women of childbearing potential in clinical trials.¹²⁰ Such committees already exist as regards research involving animals¹²¹ and genetic research.¹²² It has been suggested that the committee would be established by the BÄK and would coordinate discussion of cases which raise sufficient doubt as to their ethical propriety, examples of which would include research involving embryos and other forms of biotechnology.¹²³ A

¹¹⁷Schrönke / Schröder, fn 114 at Rn. 50a zu § 223 StGB.

¹¹⁸§ 224 StGB.

¹¹⁹§ 223 StGB.

¹²⁰Kleinsorge H 'Spezielle Probleme der Ethik-Kommissionen im Zusammenhang mit der Arzneimittelpflicht' Med R 1987, 140.

¹²¹§ 15 Abs. 1 Satz 2 TierSchG of 18. 8. 1986 I, BGBl. 1319.

¹²²See § 4 GenT of 20. 6. 1990 I, BGBl. 1080.

¹²³See Kleinsorge, fn 120 above at 141.

committee of this nature would be responsible for public *Ethik-Kommissionen*; free committees would not, however, come under the remit of the national committees.

The possibility of establishing an ethics committee at Federal level (*Bundes-Ethik-Kommission*) has also been raised particularly with reference to the human genome project. The main political parties, the CDU and the SPD, are in favour of setting up a committee of this kind and have already established a working party to investigate proposals for reform.¹²⁴

The rationale for reform is, however, inherently elitist to the extent that the public remain excluded from the decision-making process;

“Institutionelle Innovationen, die in der Lage wären, die Diskurse kritischer Initiativen, staatlicher Instanzen, der Wissenschaft und der allgemeinen Öffentlichkeit aufeinander zu beziehen, sind in Deutschland bisher rar.”¹²⁵

Indeed, the drive to set up such a national committee is comparable with the ‘QUANGO trend’ in the United Kingdom which allows the state to abdicate its responsibility to experts whilst, at the same time, being seen to be doing something about the need to regulate. To this extent, the shoe of an ‘alibi institution’ fits the *Ethik-Kommissionen*. A typical German illustration would be the *Treuhandgesellschaft GmbH*, an agency established in 1990¹²⁶ entrusted with the privatisation of property after the fall of the Berlin wall.¹²⁷ The abdication of responsibility is a universal government ploy.¹²⁸

¹²⁴See *Das Parlament* 30. 9. 1994 No. 39 p. 11 which reports the arguments of a CDU member of Parliament who stated that such a committee would have to be independent to the extent that it would be immune from the effects of electioneering. The SPD have come up with a proposal that the committee ought to have 21 members and have further stated that the committee would have an advisory role in passing on recommendation to the Parliament.

¹²⁵“Institutional innovation which would be in the position to relate critical discourses of initiatives, public authorities, science and the general public are rare in Germany.” Hennen, fn 1 above at 173.

¹²⁶Gesetz zur Privatisierung und Reorganisation des volkseigenen Vermögens (Treuhandgesetz) of 17. 6. 1990, I BGBl 300.

¹²⁷For an informative analysis of the role of the Treuhand see Southern, D B ‘Restitution or Compensation; the Land Question in East Germany’ (1993) 42 ICLQ 690.

¹²⁸“The creation of the *Treuhand* was one of the clever things the politicians did...It got blamed for everything that went wrong in the eastern German economy. And when it goes, it will take the blame with it.” Wolf Schöde in the *Independent on Sunday* January 8, 1995.

6.5. CONCLUSION

The German Drugs Code is not as strict as its regulatory nature might imply. It is, for example, far more pragmatic than is the regulation of animal experimentation¹²⁹ or embryo research.¹³⁰ It is arguable that animals are afforded greater protection than are human beings. Be that as it may, it is equally arguable that medical research in Germany is over-regulated and that, as a consequence, some forms of research are slowed down, and in some areas even paralysed.¹³¹ The type of research which the Drugs Code classifies as dubious, may be driven underground. The strict nature of the code might also encourage those who finance research to indulge in forum shopping in seeking locations for research where the regulations are more flexible.¹³² It has already been noted that Germany has experienced a 'brain drain' of medical researchers who have found alternative environments in which to conduct the type of research which is disallowed in Germany. Thus, it is in Germany's interest to ensure that its regulations are not self-defeating. This also applies to the other member states of the European Union. A uniform policy as regards the regulation of medical research is called for. The position in which the regulation of medical research is more stringent in some member states than in others is incompatible with a single market. It is not suggested, however, that the member state with the most flexible regulations should set the standard for such a regulation. A European consensus is needed - that is, a consensus of the citizens of Europe. It is questionable, however, whether 'citizens' will, in practice, be defined

¹²⁹See the Tierschutzgesetz of 18. 8. 1986 BGBl. I, 1319.

¹³⁰Embryonenschutzgesetz of 13. 12. 1990, BGBl. I, 2746.

¹³¹As in the case of research involving children and the incompetent.

¹³²Concept derived from Private International Law. See North, P M and Fawcett, J J *Cheshire and North: Private International Law* (11th edn, 1987).

widely as opposed to being umbilically fed by the professions - given the democratic deficit within the institutions of the European Union.

CHAPTER SEVEN

CONCLUSION

The prevalence of unethical research knows no national boundaries - it is not exclusively a German phenomenon. In direct contrast to the United States, however, Germany is still trying to make amends and is trying to show that the history of the Third Reich will not repeat itself. This explains the exaggerated response to issues such as embryo research or to cloning.¹ The United States, however, affects a stance of selective amnesia concerning its role in unethical research. Quite how the American public can rationalise *Tuskegee*, or *Hyman*, or its involvement in cases of dubious research which was carried out in Japanese prisoner of war camps,² is an enigma which merits more scrutiny than it has hitherto been granted.³ This comment is made in the light of the recent public apologies by President Clinton to survivors of the *Tuskegee* experiments, some 65 years after their commencement and to the survivors of the Cold War experiments in 1995.⁴ It is also made in the light of the move by the Food and Drug Administration (FDA) to allow informed consent to be waived in an emergency when a patient, unrepresented by a legal guardian, is unconscious and critically ill with a condition that is unlikely to be improved by conventional means and which could reasonably be expected to benefit from experimental therapy.⁵

¹See 'Vernichtung von Embryonen in Großbritannien' *Frankfurter Allgemeine Zeitung* August 2, 1996 and also Kirschbaum, E 'Germans on their high horse over cloned sheep' *The Guardian* March 6, 1997 at p. 11.

²Capron, A M 'Human Experimentation' in Veatch, R (ed) *Medical Ethics* (1989) at p. 137 et seq.

³See *The Economist* May 17, 1997 at p. 53.

⁴See *The Washington Post* April 9, 1997 at pp 1, 9.

⁵Editorial (1996) 348 *Lancet*.

7.1. SOCIETAL RESPONSIBILITY

Medical research has traditionally been discussed in terms of fault, most of which has been placed on the shoulders of the medical profession. According to tradition, the question is posed in terms of why did the doctors engage in research which is clearly unethical? This is an important question and should continue to be asked by succeeding generations. Perhaps the physicians who engaged in research of a most abhorrent nature during the Third Reich were 'unthinking'. Evidence which came to light during the Nuremberg Trial, however, indicated that the physicians believed that their actions were justified. Indeed, the American Cold War 'régime' encouraged medical researchers to conduct their experiments as part of the 'war effort' and to rationalise them as being in the national interest.

An analysis of the phenomenon of unethical research cannot be limited to the notion of the unreflective physician alone. The role and conduct of society should also be questioned, as a recent controversial book dealing with the Holocaust illustrates. In *Hitler's Willing Executioners*, Daniel Goldhagen writes persuasively of the overall involvement of the public in following the tenets of national socialism to their logical conclusions.⁶ We can apply Goldhagen's thinking to the responsibility of unethical research. The professional élite in both Germany and the United States, played a vital role in justifying the conduct of research which would now be seen as being unacceptable. The German legal system, for example, was not a victim of national socialism but was an accomplice in that lawyers actively promoted its ideology.⁷ The same can be said of some American judges at the height of the Cold War.⁸ But if the professions have traditionally been accomplices in the history of unethical research, so

⁶(1996).

⁷See Müller, I *Furchtbare Juristen* (1989) and also Rottleuthner, H 'Substantieller Dezisionismus zur Funktion der Rechtsphilosophie im Nationalsozialismus' (1983) *Arch Rechts-und Sozialph/Beiheft* 18, 20.

⁸*United States v. Stanley* 483 U.S. 669, 798 (1987) also in Annas, G J 'The Nuremberg Code in U.S. Courts: Ethics Versus Expediency' in Annas, G J and Grodin, M A (eds) *The Nazi Doctors and the Nuremberg Code* (1992) at 201 and 214.

too have the general public. Its existence is matter for societal consciousness and conscience.⁹ The regulation of medical research should not be framed in terms of fault or blame as this allows the individual to stand back and abdicate responsibility for something *which affects us collectively*. Although they are not necessarily self exclusive, responsibility, not blame, should be the rationale for the regulation of medical research.

7.2. THE MEDICAL RESEARCH DEBATE

Those who participate in the medical research debate are not, in general, elected representatives of the people. They are largely self-appointed and as a result the principles on which research is based are not the product of full and open debate. On the contrary, the medical research process is pervaded by a lack of transparency and it is inherently undemocratic.

Scientists have taken charge of defining risks and will accept criticism of their methods only from other scientists. At the end of the day, lawyers are in charge of the legality of the process because it is seen as being umbilically linked to medical negligence. Moral philosophers or professional 'bioethicists' have commandeered the infrastructure of research ethics. The general public are excluded from the process of establishing the normative principles. Dialogue between the professions and the rest of society is essential.

⁹As was stated at the time of the 50th anniversary of the Dresden bombing; "“Wenn ich mich an den Ersten Weltkrieg oder an den Zweiten Weltkrieg erinnere, dann ist damit zunächst einmal einfach das Entsetzen darüber verbunden was Menschen sich gegenseitig angetan haben. Man müsse sich immer wieder an die Vergangenheit erinnern. Man muß daran denken, erstens um zu wissen, in welcher relativ glücklichen Welt wir leben, und auch um zu wissen was der Mensch, wenn er nicht aufpaßt, anstellen kann. Das es der Sinn der Erinnerns”. Or “When I remember the first or the second World War, at first I feel shocked at what people did to eachother. One must always remember the past. One must think about the relatively lucky world we live in and also what man, if he is not careful, is capable of doing.” See *Der Tagesspiegel* February 12, 1995 at p. 1.

We need the professions. We depend on them to understand the complexities which arise in the medical research process. The professions, however, should not monopolise rationality. Several observations follow.

7.2.1. SCIENTIFIC REASONING: THE NEED FOR DIALOGUE

Objective experimentation, as formally introduced by Claude Bernard,¹⁰ was never qualified in the context of medical research involving *human beings*. It is a regrettable consequence that the reasoning behind standard scientific enquiry has been extrapolated to human research. This is inappropriate and explains why medical researchers have failed to see the need for dialogue between themselves and their research subjects. Objective statements used in medical research are impersonal. Language used in an impersonal context reduces individuals to objects rather than rational human beings who are capable of making choices. The choices available to an individual used in research are translated into matters of function and manipulation instead of identity and relationship.¹¹

Dialogue is a two way process. If society is to play a role in ascertaining the principles for research, it must learn to accept scientific premises behind medical research.¹² At the same time, however, scientific reasoning must also learn to come to terms with the attitudes of society. Symbiosis must be an integral characteristic of the relationship.

7.2.2. LEGAL REASONING: THE ROLE OF THE LAW

In essence, the current regulatory framework for medical research involving human subjects is steeped in liberal individualism. Rights are rooted in medical negligence

¹⁰ Bernard, C *An Introduction to the Study of Experimental Medicine* (Copley Green, H(tr) 1957).

¹¹ Alderson, P 'Did Children Change, or did the guidelines ?' (1992) 80 Bull Med Eth 22

¹² This has been also argued by Professor Sheila McLean in relation to the Human Genome Project. See McLean, S A M 'Law, Ethics and the Human Genome Project' (1994, Edinburgh: Society of Solicitors in the Supreme Courts of Scotland Biennial Lecture) at p. 7.

which is in itself atomistic. This is not to say that individualism is wrong. The concept of individualism in medical research, must, however, be qualified by an acknowledgment of the role of other interested parties.

Common law sets standards - albeit retrospectively - on a case by case basis as opposed to an approach which is principled. The legal framework as exemplified in medical negligence should not be the exclusive model for the regulation of medical research. The legal reasoning which lies behind the control of medical treatment and which has been extrapolated to medical research involving human subjects is inappropriate given that the former is based on an "after the fact" approach.

Procedural guidelines should be established which safeguard the public interest and which enable questions of medical research to be based on deontological grounds approved within a democratic framework. A concept of rights is needed which is both realistic and sensitive to the context in which they operate. It is suggested that, as regards the medical research process, the rights of the vulnerable are better viewed in terms of the obligations of the powerful. Moreover, obligations should spread to all those in the position of fulfilling them. Thus, there should be an obligation to provide information, there should be an obligation to define the risks of a procedure and an obligation to provide an insurance scheme whereby research subjects can be compensated in the event of harm or death. Among these, the priority must be access to information because the current opacity of the medical research process must be illuminated. In particular, the ethical track record of pharmaceutical companies must be available for public scrutiny, as the Upjohn case and the Bayer case testify.¹³

The public should take part in ascertaining principles as of right and not by favour of the 'great and the good'. In short, the research debate ought to be more egalitarian and the basis for inclusion within it should be inclusionary rather than exclusionary.

¹³Brahams, D 'Upjohn (Halcion) and libel actions' (1994) *Lancet* 1422 and Teff, H 'The Law and Ethics of Medical Experimentation' (1987) *PN* 184 and also Wise, J 'Research suppressed for seven years by drug company' (1997) *314 BMJ* 1145.

7.2.3. MORAL REASONING: UNIVERSALISM AND ITS FACILITATORS

Moral philosophers or 'bioethicists' are essential as facilitators in the decision-making process concerning principles for medical research. This, however, is some way from accepting that they should bear the sole responsibility for ascertaining ethical norms of medical research. It is essential that a universal position is adopted - but the abolition of privilege and discrimination in medical research can only be achieved if the consequences of universalisation satisfy the interests of all those affected.¹⁴ Habermas' theory of debate ethics serves as an appropriate model upon which to achieve societal responsibility when ascertaining the principles of medical research. Moral reasoning must, therefore, be concerned with procedure rather than with substance.¹⁵ The role of philosophers in the research debate is not to provide the public with answers but, rather, to develop a method whereby questions raised by research can be addressed by disclosing the underlying principles.

7.3. RESEARCH ETHICS COMMITTEES

7.3.1. RESEARCH ETHICS COMMITTEES IN THE UNITED KINGDOM

Several measures are suggested in order to redress the democratic deficit which pervades the regulation of medical research. First, a statute should be enacted which places research ethics committees on a proper legal footing. Establishing research ethics committees by force of law recognises their importance as the main model of accountability for research. Guidelines established by Act of Parliament are bound to be

¹⁴See Habermas, J *Between Facts and Norms: Contributions to a Discourse Theory of Law and Democracy* (1996) at 12.

¹⁵Whilst procedure is a universal, substance is subject to modification at a grass roots level.

more detailed and authoritative than are those dependent on no more than a departmental circular.¹⁶

Measures should be introduced whereby certain provisions, such as data bases for both researchers and research subjects at a national and European level - which is especially important in the case of multicentre trials - are formalised. Moreover, there should be a right to information based on an obligation to provide information concerning the research. Examination of the *Child B* case indicates that the responsibility to provide information must not be in the hands of one party, given the likelihood of selective presentation by those involved.¹⁷ In general, medical information should be made available only on a "need to know" basis but, in the particular case of research it is the public as a whole who "need to know".¹⁸ The bill of rights for research which exists in California¹⁹ provides an appropriate base for the enactment of such measures. It is suggested, however, that guidelines operating in the United Kingdom should be for the benefit not only of research subjects but also of medical researchers and other interested parties.

Lay members for RECs must include a wider cross - section of the community, as is the case in Childrens Panel in Scotland where the experience of laypersons is emphasised as opposed to linking membership to a professional benchmark.

Closer co-operation with the Department of Health as a supervisory and advisory service which could be contacted in the event of unease on the part of a committee or an

¹⁶See the disparate Police and Criminal Act 1984 and the Human Fertilisation and Embryology Act 1990.

¹⁷Entwistle, V A, Watt, I S, Bradbury, R, Pehl Lesley, J 'Media coverage of the Child B case' (1966) 312 BMJ 1588.

¹⁸Nicholson makes this point in relation to research ethics committees and members of the public: "Members of the public may wish to know who are the people with the responsibility to protect their interests but may also be more likely to want to know what research is being undertaken on people with their particular medical problem - either because they wish to become altruistically involved, or because they want to know whether they might have been unwitting "guinea pigs" on their last trip to hospital." See Nicholson, R 'What do they get up to ? LREC annual reports' (1997) 129 Bull Med Eth 13 at 21.

¹⁹Myers, D *The Human Body and the Law* (2nd edn, 1990) at 247.

individual committee member is called for. The former could arise in the context of a multicentre project; the latter might result from approval by way of majority voting.

As regards accountability of research ethics committees, the principles of openness, transparency and reasonableness may be found in the context of judicial review. This, with its concentration on procedural fairness and demonstrated rationality, provides a route towards ensuring legality of the decisions taken. Creating an obligation for a body to give reasons for its decisions is beneficial as it ensures that the standards according to which researchers are judged are exposed to public debate and scrutiny.

Models such as a national research ethics committee, as well as a national independent review committee for medical research, must be considered in the light of the apparent success of statutory bodies such as the Human Fertilisation and Embryology Authority. Many such suggestions for reform have been made including the creation of a national commission²⁰ responsible for monitoring the entire field of medicine, law and ethics; the remit of the commission could be to identify specific medical issues with major ethical implications and to elaborate a national policy on such issues whether they arise in a hospital or in a commercial context. Nonetheless, there is a distinct difference between such a group and an authority established by Act of Parliament and as I have argued in Chapter Six the former should be advisory only and should not arrogate to itself the supervisory powers of the latter.

It has been argued that the professions are invaluable assets in the decision-making process of medical research. However, the division of labour inherent in ascertaining norms for medical research must be restructured. Equivalent precedence must be given to the contribution that public understanding has to make to structures such as research ethics committees and a national research ethics committee - should one ever be established. Thus, a national committee should also co-operate with parallel structures

²⁰Teff, H 'The Law and Ethics of Medical Experimentation' (1987) PN 184.

such as Citizens' Juries so that committees can be informed of public opinion regarding the questions raised by medical research.

7.3.2. RESEARCH ETHICS COMMITTEES IN GERMANY

Most - if not all - of the conclusions drawn above also apply to the regulation of medical research in Germany. However, several more observations arise. Whereas *Ethik-Kommissionen* are established by law, the regulation can still be described as "soft law" to the extent that it leaves matters concerning practice up to the discretion of the committees. The statutes regulating genetic engineering²¹ (*Gentechnikgesetz*) and the protection of animals²² (*Tierschutzgesetz*) give research ethics committees less discretion. It is suggested that the existing regulatory position in both the United Kingdom and in Germany could be reformed using the structures provided by the *Gentechnikgesetz* and the *Tierschutzgesetz* as lines of departure given the far greater detail as regards the composition and practices for research ethics committees that is provided by these regulations.

We can go one stage further and call for uniformity as regards the regulation of medical research within the European Union. It has been suggested that Germany's high regulatory standards might be undermined by other Member States adopting measures which are less stringent - it would then become progressively more difficult for the member states with strict regulations to maintain their standards particularly in the commercial field. Standards should not, however, be evaded. An invitation is hereby extended to the Council of Ministers to adopt a legislative response to the issues which are raised by the regulation of medical research conducted within the European Union.

²¹See Riedel E, 'The Constitution and Scientific and Technical Progress' (1991) in Starck, C (ed) *New Challenges to the German Basic Law* (1991) at p. 68.

²²*Tierschutzgesetz* of 18. 8. 1986 BGBl. I, 1319.

7.4. CODA

In conclusion, the regulation of medical research involving human subjects must be restructured along procedural lines. To this extent, this thesis is one based on process. It is firmly believed that process will enable the substantive principles for medical research to be the product of democratic consensus. The rationale for the regulation of medical research involving human subjects should be based on the adage that: principles governing medical research should arise out of the people as opposed to being created *over* the people.

APPENDIX A

GERMAN SOURCES OF LAW¹

The Constitution

The 1949 Bonn constitution or the Basic Law (*Grundgesetz*) is very much a product of the era after the second World War. This explains the paramountcy of human rights and human dignity which lie at the heart of the provisions of the basic law; it also explains the stringent protection afforded individuals involved in medical research.

The constitution is at the apex of the hierarchy of the German sources of law. An emphasis of the Basic Law is the protection of human and civil rights (*Grundrechte*). This protection is furthered by the Federal Constitutional Court (*Bundesverfassungsgericht*) which is empowered, *inter alia*, to review the constitutionality of Federal law and the laws of the individual states (*Länder*) in the light of the *Grundrechte*.

The constitution includes specific provisions which emphasise social justice in the sense of social equality and the realisation of freedom under the rule of law. Article 20 (1) of the basic law provides that the Federal Republic is a state based on the rule of law (*Rechtsstaat*) which is to be exercised within the parameters of the welfare state (*Sozialstaat*).²

The concept of the *Rechtsstaat* demands that all state activities are based on laws as contained in the constitution. The legal basis for the *Sozialstaat* is set out in Arts. 20 (1) and 79 (3) of the Basic Law. The provisions include, *inter alia*, that the Federation and the *Länder* must take the overall economic equilibrium into account as part of their fiscal

¹The major source for this section is Foster, N *German Law and Legal System* (1993). See p. 46.

² See Stein, E *Staatsrecht* (14 edn, 1993) at § 24 IV at p. 204 et seq.

administration. This includes all the basic rights to human dignity, free development of personality and equality before the law.

The Codes

The German legal system is further governed by a constitutional ranking of norms which has constitutional law as its apex with the codes (*Gesetz*), directly beneath. The codes referred to throughout this work³ provide the legal framework in which the control of medical research involving human subjects in Germany must be viewed. The codes provide definitive answers to specific legal problems; consultation of the commentaries (*Kommentar*) is a legal imperative.

The Kommentar

The commentaries explain and interpret the codes.⁴ They are written by leading academics and judges and are cited as legal authorities in court.⁵ In contrast to their English counterparts, writers such as Bracton and Blackstone notwithstanding, Scottish lawyers would have no difficulty in placing this practice into legal context in view of the tradition of institutional writing in Scotland; this is because of the influence of Roman law, by which the common law in England remained largely unaffected.⁶ Thus, mirroring

³For example the Basic Law (*Grundgesetz*), the Drugs Code (*Arzneimittelgesetz*), the Civil Code (*Bürgerliches Gesetz Buch*) and the Criminal Code (*Straf Gesetz Buch*).

⁴For example see the commentary by von Münch, I and Kunig, P *Grundgesetz Kommentar* (4th edn, 1992).

⁵A comparable example in England & Wales would be the annotated statute collections of *Halsbury* or *Statutes in force* although the German versions go into far greater detail and analysis which is more comparable to *Stairs Encyclopaedia* in Scotland.

⁶Although see *Krell v. Henry* [1903] 2 KB 740 at p. 747 *et seq* which illustrates the application in English law of a Roman law principle, *debitor speciei liberator casuali interitus rei* (the debtor is relieved of his duty to deliver the object if it has been destroyed through no fault of his own. During the nineteenth century, English judges began to interpret this rule as forming part of parties' agreements. See also *Taylor v. Caldwell* (1863) 3 B & S 826. A further example is the doctrine of frustration which corresponds to *clausula rebus sic stantibus*. See Zimmerman, R *The Law of Obligations; Roman Foundations of the Civilian Tradition* (1990) at p. 579 *et seq*.

the position in Germany, much of Scots law is based on the institutional writers.⁷ Lord Stair's *Institutions* is cited as persuasive authority to this day and can be described as forming part of the law of Scotland.

Academic Legal Opinion

Historically, universities played an important role in the development and the systemisation of German law which is reflected by the influential role of German legal literature. Academic opinion, outlined in periodicals is regarded as persuasive authority. This is in direct contrast to the position in common law jurisdictions.⁸ The position in Scotland can be distinguished on the grounds that it is more common to cite the opinions of academics, which may influence the outcome of litigation.

Case Law

Strictly speaking, case law is not a formal source of law; it is interpretative only.⁹ The guiding principle is that judges should simply apply the law and should not create it;¹⁰ needless to say this involves a considerable degree of interpretation. The German legal system, as opposed to its common law counterpart, does not rely on the doctrine of precedent (*Präjudizien*); court decisions apply to that case only and have no general binding effect in other cases.¹¹

⁷Influences of Roman law, however, varied. See for example the distinction drawn by Zweigert and Kötz between Germanic and Romanistic legal families. Zweigert, K and Kötz, H *Introduction to Comparative Law* (1992, Weir, T (tr)) at p. 63.

⁸See however Lord Goff in *Spiliarda Maritime v. Consulex Ltd* [1987] 1 AC 460 at p. 488.

Although academics have recently been cited in some recent House of Lords decisions (notably by Lord Goff). Furthermore, the situation in Scotland differs in that academic legal opinion is being relied upon more and more and references are commonly made to *Stairs Encyclopaedia* which is for the most part, written by academics.

⁹The importance of case law must not, however, be overlooked. See Zimmerman, R 'An Introduction to German Legal Culture' in Ebke, W and Finkin, M W (eds) *Introduction to German Law* (1996) at pp 27 *et seq.*

¹⁰Marsh N 'Some aspects of the German legal system under National Socialism' (1946) 62 LQR, pp. 366-74.

¹¹See however article 94 Abs. 2 of the Basic Law which relates to decisions of the Constitutional Court (*Bundesverfassungsgericht: BVerfG*) and generally Foster, fn 1 above at 55-56 for the exceptions to this rule.

Abbreviations

AMG	<i>Arzneimittelgesetz</i>	German Drugs Code
BGB	<i>Bürgerliches Gesetzbuch</i>	German Civil Code
BGH	<i>Bundesgerichtshof</i>	Germany's Federal Supreme Court ¹²
BGHZ	<i>Entscheidungen des Bundesgerichtshof in Zivilsachen</i>	Decisions of the German Supreme Court in civil matters
BTG	<i>Betreuungsbehördengesetz</i>	Statute for care assistantship supervisory authorities
BVerG	<i>Bundesverfassungsgericht</i>	Federal Constitutional Court (FCA)
BVerGE	<i>Entscheidungen des BVerG</i>	FCA decisions
BVerGG	<i>Bundesverfassungsgerichtsgesetz</i>	Statute of the Constitutional Court of the FRG
FGG	<i>Gesetz über die Angelegenheiten der freiwilligen Gerichtsbarkeit</i>	Statute
GG	<i>Grund Gesetz</i>	The Basic Law
NJ	<i>Neue Justiz</i>	Periodical
<i>NJW</i>	<i>Neue Juristische Wochenschrift</i>	Periodical
StGB	<i>Strafgesetzbuch</i>	German Criminal Code

¹²Before 'Re-unification' of 1990, the BGH was the Supreme (Civil and Criminal) Court for Western Germany only.

APPENDIX B

THE NUREMBERG CODE (1947)

Permissible medical experiments

The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their view on the basis that such experiments yield results for the good of society that are unprocureable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and all the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocureable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except perhaps, in those experiments where the experimental physicians also serve as the subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made, and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he had reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

APPENDIX C

DECLARATION OF HELSINKI (REVISED 1975)

RECOMMENDATIONS GUIDING MEDICAL DOCTORS IN BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

Introduction

It is the mission of the medical doctor to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfilment of this mission.

The Declaration of Geneva of the World Medical Association binds the doctor with the words: 'The health of my patient will be my first consideration,' and the International Code of Medical Ethics declares that, 'Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest.'

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies *a fortiori* to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects. In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research the essential object of which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every doctor in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. Basic Principles

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific tradition.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under supervision of a clinically competent medical person. The responsibility for the

human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interest of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

7. Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Doctors should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the doctor is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research in human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The doctor should then obtain the subject's freely-given informed consent, preferably in writing.

10. When obtaining consent for the research project the doctor should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a doctor who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. Medical Research Combined with Professional Care (Clinical Research)

1. In the treatment of the sick person, the doctor must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, re-establishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method.

4. The refusal of the patient to participate in a study must never interfere with the doctor-patient relationship.

5.If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee.

6.The doctor can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III.Non-therapeutic Biomedical Research Involving Human Subjects (Non-clinical biomedical research)

1.In the purely scientific application of medical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom biomedical research is carried out.

2.The subjects should be volunteers - either healthy persons or patients for whom the experimental design is not related to the patient's illness.

3.The investigator or the investigating team should discontinue the research if in his / her judgment it may, if continued, be harmful to the individual.

4.In research on man, the interest of science and society should never take precedence over considerations related to the wellbeing of the subject.

3. das Arzneimittel nicht die nach den anerkannten pharmazeutischen Regeln angemessene Qualität aufweist,
4. bei dem Arzneimittel der begründete Verdacht besteht, daß es bei bestimmungsgemäßem Gebrauch schädliche Wirkungen hat, die über ein nach den Erkenntnissen der medizinischen Wissenschaft vertretbares Maß hinausgehen,
- 4a. das Arzneimittel zur Anwendung bei Tieren bestimmt ist, die der Gewinnung von Lebensmitteln dienen,
5. die angegebene Wartezeit nicht ausreicht,
- 5a. das Arzneimittel, sofern es zur Anwendung bei Menschen bestimmt ist, nicht zur Einnahme und nicht zur äußerlichen Anwendung bestimmt ist,
6. das Arzneimittel der Verschreibungspflicht unterliegt,
7. das Arzneimittel nicht nach einer im Homöopathischen Teil des Arzneibuches beschriebenen Verfahrenstechnik hergestellt ist,
- 7a. wenn die Anwendung als homöopathisches oder anthroposophisches Arzneimittel nicht allgemein bekannt ist,
8. für das Arzneimittel eine Zulassung erteilt ist,
9. das Inverkehrbringen des Arzneimittels gegen gesetzliche Vorschriften verstoßen würde.

(2a) Ist das Arzneimittel bereits in einem anderen Mitgliedstaat der Europäischen Gemeinschaften oder in einem anderen Vertragsstaat des Abkommens über den Europäischen Wirtschaftsraum registriert worden, ist die Registrierung auf der Grundlage dieser Entscheidung zu erteilen, es sei denn, daß ein Versagungsgrund nach Absatz 2 vorliegt.

(2b) Die Registrierung erlischt nach Ablauf von fünf Jahren seit ihrer Erteilung, es sei denn, daß drei bis sechs Monate vor Ablauf der Frist ein Antrag auf Verlängerung gestellt wird. Für die Verlängerung der Registrierung gilt § 31 Abs. 2 bis 4 entsprechend mit der Maßgabe, daß die Versagungsgründe nach Absatz 2 Nr. 3 bis 9 Anwendung finden.

(3) Das Bundesministerium wird ermächtigt, durch Rechtsverordnung mit Zustimmung des Bundesrates Vorschriften über die Anzeigepflicht, die Neuregistrierung, die Löschung, die Kosten, die Bekanntmachung und die Freistellung von der Registrierung homöopathischer Arzneimittel entsprechend den Vorschriften über die Zulassung zu erlassen. Die Rechtsverordnung ergeht im Einvernehmen mit dem Bundesministerium für Ernährung, Landwirtschaft und Forsten, soweit es sich um Arzneimittel handelt, die zur Anwendung bei Tieren bestimmt sind.

Sechster Abschnitt

Schutz des Menschen bei der klinischen Prüfung

§ 40

Allgemeine Voraussetzungen

(1)* Die klinische Prüfung eines Arzneimittels darf bei Menschen nur durchgeführt werden, wenn und solange

1. die Risiken, die mit ihr für die Person verbunden sind, bei der sie durchgeführt werden soll, gemessen an der voraussichtlichen Bedeutung des Arzneimittels für die Heilkunde, ärztlich vertretbar sind,
2. die Person, bei der sie durchgeführt werden soll, ihre Einwilligung hierzu erteilt hat, nachdem sie durch einen Arzt über Wesen, Bedeutung und Tragweite der klinischen Prüfung aufgeklärt worden ist,
3. die Person, bei der sie durchgeführt werden soll, nicht auf gerichtliche oder behördliche Anordnung in einer Anstalt verwahrt ist,
4. sie von einem Arzt geleitet wird, der mindestens eine zweijährige Erfahrung in der klinischen Prüfung von Arzneimitteln nachweisen kann,
5. eine dem jeweiligen Stand der wissenschaftlichen Erkenntnisse entsprechende pharmakologisch-toxikologische Prüfung durchgeführt worden ist,
6. die Unterlagen über die pharmakologisch-toxikologische Prüfung bei der zuständigen Bundesoberbehörde hinterlegt sind,

*) Gemäß Artikel 1 Nr. 25 Buchstabe a in Verbindung mit Artikel 6 Abs. 2 Nr. 1 des Fünften Gesetzes zur Änderung des Arzneimittelgesetzes vom 9. August 1994 (BGBl. I S. 2071) wird § 40 Abs. 1 mit Wirkung vom 17. August 1995 wie folgt gefaßt:

„(1) Die klinische Prüfung eines Arzneimittels darf bei Menschen nur durchgeführt werden, wenn und solange

1. die Risiken, die mit ihr für die Person verbunden sind, bei der sie durchgeführt werden soll, gemessen an der voraussichtlichen Bedeutung des Arzneimittels für die Heilkunde ärztlich vertretbar sind,
2. die Person, bei der sie durchgeführt werden soll, ihre Einwilligung hierzu erteilt hat, nachdem sie durch einen Arzt über Wesen, Bedeutung und Tragweite der klinischen Prüfung aufgeklärt worden ist, und mit dieser Einwilligung zugleich erklärt, daß sie mit der im Rahmen der klinischen Prüfung erfolgenden Aufzeichnung von Krankheitsdaten und ihrer Weitergabe zur Überprüfung an den Auftraggeber, an die zuständige Überwachungsbehörde oder die zuständige Bundesoberbehörde einverstanden ist,
3. die Person, bei der sie durchgeführt werden soll, nicht auf gerichtliche oder behördliche Anordnung in einer Anstalt untergebracht ist,
4. sie von einem Arzt geleitet wird, der mindestens eine zweijährige Erfahrung in der klinischen Prüfung von Arzneimitteln nachweisen kann,
5. eine dem jeweiligen Stand der wissenschaftlichen Erkenntnisse entsprechende pharmakologisch-toxikologische Prüfung durchgeführt worden ist,
6. die Unterlagen über die pharmakologisch-toxikologische Prüfung, der dem jeweiligen Stand der wissenschaftlichen Erkenntnisse entsprechende Prüfplan mit Angabe von Prüfern und Prüforten und die Voten der Ethik-Kommissionen bei der zuständigen Bundesoberbehörde vorgelegt worden sind,
7. der Leiter der klinischen Prüfung durch einen für die pharmakologisch-toxikologische Prüfung verantwortlichen Wissenschaftler über die Ergebnisse der pharmakologisch-toxikologischen Prüfung und die voraussichtlich mit der klinischen Prüfung verbundenen Risiken informiert worden ist und
8. für den Fall, daß bei der Durchführung der klinischen Prüfung ein Mensch getötet oder der Körper oder die Gesundheit eines Menschen verletzt wird, eine Versicherung nach Maßgabe des Absatzes 3 besteht, die auch Leistungen gewährt, wenn kein anderer für den Schaden haftet.

Die klinische Prüfung eines Arzneimittels darf bei Menschen vorbehaltlich des Satzes 3 nur begonnen werden, wenn diese zuvor von einer nach Landesrecht gebildeten unabhängigen Ethik-Kommission zustimmend bewertet worden ist; Voraussetzung einer zustimmenden Bewertung ist die Einhaltung der Bedingungen in Satz 1. Soweit keine zustimmende Bewertung der Ethik-Kommission vorliegt, darf mit der klinischen Prüfung erst begonnen werden, wenn die zuständige Bundesoberbehörde innerhalb von 60 Tagen nach Eingang der Unterlagen nach Satz 1 Nr. 6 nicht widersprochen hat. Über alle schwerwiegenden oder unerwarteten unerwünschten Ereignisse, die während der Studie auftreten und die Sicherheit der Studienteilnehmer oder die Durchführung der Studie beeinträchtigen könnten, muß die Ethik-Kommission unterrichtet werden.“

7. der Leiter der klinischen Prüfung durch einen für die pharmakologisch-toxikologische Prüfung verantwortlichen Wissenschaftler über die Ergebnisse der pharmakologisch-toxikologischen Prüfung und die voraussichtlich mit der klinischen Prüfung verbundenen Risiken informiert worden ist,

7a. ein dem jeweiligen Stand der wissenschaftlichen Erkenntnisse entsprechender Prüfplan vorhanden ist und

8. für den Fall, daß bei der Durchführung der klinischen Prüfung ein Mensch getötet oder der Körper oder die Gesundheit eines Menschen verletzt wird, eine Versicherung nach Maßgabe des Absatzes 3 besteht, die auch Leistungen gewährt, wenn kein anderer für den Schaden haftet.

(2) Eine Einwilligung nach Absatz 1 Nr. 2 ist nur wirksam, wenn die Person, die sie abgibt

1. geschäftsfähig und in der Lage ist, Wesen, Bedeutung und Tragweite der klinischen Prüfung einzusehen und ihren Willen hiernach zu bestimmen und
2. die Einwilligung selbst und schriftlich erteilt hat.

Eine Einwilligung kann jederzeit widerrufen werden.

(3) Die Versicherung nach Absatz 1 Nr. 8 muß zugunsten der von der klinischen Prüfung betroffenen Person bei einem im Geltungsbereich dieses Gesetzes zum Geschäftsbetrieb zugelassenen Versicherer genommen werden. Ihr Umfang muß in einem angemessenen Verhältnis zu den mit der klinischen Prüfung verbundenen Risiken stehen und für den Fall des Todes oder der dauernden Erwerbsunfähigkeit mindestens eine Million Deutsche Mark betragen. Soweit aus der Versicherung geleistet wird, erlischt ein Anspruch auf Schadensersatz.

(4) Auf eine klinische Prüfung bei Minderjährigen finden die Absätze 1 bis 3 mit folgender Maßgabe Anwendung:

1. Das Arzneimittel muß zum Erkennen oder zum Verhüten von Krankheiten bei Minderjährigen bestimmt sein.
2. Die Anwendung des Arzneimittels muß nach den Erkenntnissen der medizinischen Wissenschaft angezeigt sein, um bei dem Minderjährigen Krankheiten zu erkennen oder ihn vor Krankheiten zu schützen.
3. Die klinische Prüfung an Erwachsenen darf nach den Erkenntnissen der medizinischen Wissenschaft keine ausreichenden Prüfergebnisse erwarten lassen.
4. Die Einwilligung wird durch den gesetzlichen Vertreter oder Pfleger abgegeben. Sie ist nur wirksam, wenn dieser durch einen Arzt über Wesen, Bedeutung und Tragweite der klinischen Prüfung aufgeklärt worden ist. Ist der Minderjährige in der Lage, Wesen, Bedeutung und Tragweite der klinischen Prüfung einzusehen und seinen Willen hiernach zu bestimmen, so ist auch seine schriftliche Einwilligung erforderlich.

(5) Das Bundesministerium wird ermächtigt, durch Rechtsverordnung mit Zustimmung des Bundesrates Regelungen zur Gewährleistung der ordnungsgemäßen Durchführung der klinischen Prüfung und der Erzielung dem wissenschaftlichen Erkenntnisstand entsprechender Unterlagen zu treffen. In der Rechtsverordnung können

insbesondere die Aufgaben und Verantwortungsbereiche der Personen, die die klinische Prüfung veranlassen, durchführen oder kontrollieren, näher bestimmt und Anforderungen an das Führen und Aufbewahren von Nachweisen gestellt werden.

§ 41

Besondere Voraussetzungen

Auf eine klinische Prüfung bei einer Person, die an einer Krankheit leidet, zu deren Behebung das zu prüfende Arzneimittel angewendet werden soll, findet § 40 Abs. 1 bis 3 mit folgender Maßgabe Anwendung:

1. Die klinische Prüfung darf nur durchgeführt werden, wenn die Anwendung des zu prüfenden Arzneimittels nach den Erkenntnissen der medizinischen Wissenschaft angezeigt ist, um das Leben des Kranken zu retten, seine Gesundheit wiederherzustellen oder sein Leiden zu erleichtern.
2. Die klinische Prüfung darf auch bei einer Person, die geschäftsunfähig oder in der Geschäftsfähigkeit beschränkt ist, durchgeführt werden.
3. Ist eine geschäftsunfähige oder in der Geschäftsfähigkeit beschränkte Person in der Lage, Wesen, Bedeutung und Tragweite der klinischen Prüfung einzusehen und ihren Willen hiernach zu bestimmen, so bedarf die klinische Prüfung neben einer erforderlichen Einwilligung dieser Person der Einwilligung ihres gesetzlichen Vertreters.
4. Ist der Kranke nicht fähig, Wesen, Bedeutung und Tragweite der klinischen Prüfung einzusehen und seinen Willen hiernach zu bestimmen, so genügt die Einwilligung seines gesetzlichen Vertreters.
5. Die Einwilligung des gesetzlichen Vertreters ist nur wirksam, wenn dieser durch einen Arzt über Wesen, Bedeutung und Tragweite der klinischen Prüfung aufgeklärt worden ist. Auf den Widerruf findet § 40 Abs. 2 Satz 2 Anwendung. Der Einwilligung des gesetzlichen Vertreters bedarf es solange nicht, als eine Behandlung ohne Aufschub erforderlich ist, um das Leben des Kranken zu retten, seine Gesundheit wiederherzustellen oder sein Leiden zu erleichtern, und eine Erklärung über die Einwilligung nicht herbeigeführt werden kann.
6. Die Einwilligung des Kranken, des gesetzlichen Vertreters ist auch wirksam, wenn sie mündlich gegenüber dem behandelnden Arzt in Gegenwart eines Zeugen abgegeben wird.
7. Die Aufklärung und die Einwilligung des Kranken können in besonders schweren Fällen entfallen, wenn durch die Aufklärung der Behandlungserfolg nach der Nummer 1 gefährdet würde und ein entgegenstehender Wille des Kranken nicht erkennbar ist.

§ 42

Ausnahmen

Die §§ 40 und 41 finden keine Anwendung bei Arzneimitteln im Sinne des § 2 Abs. 2 Nr. 1a, 3 und 4. § 40 Abs. 1 Nr. 5 und 6 findet keine Anwendung auf klinische Prüfungen mit zugelassenen oder von der Zulassungspflicht freigestellten Arzneimitteln.

§§ 40 AND 41 OF THE ARZNEIMITTELGESETZ (AMG)¹³

§ 40 General Provisions

(1) The clinical trial of a medicine may only be conducted providing

1. the risks which are connected to the individual upon whom the trial will be carried out are justifiable in relation to the foreseeable impact of the medicine on medical science,

2. the person upon whom the trial will be carried out has given his consent after having been informed of the nature, meaning and consequences of the clinical trial,

3. the person upon whom the trial will be carried out is not legally committed by a court or an authority to an institution,

4. the supervisor of the clinical trial has at least two years experience in clinical trials of medicines,

5. corresponding pharmacological-toxicological tests have been conducted in accordance with current scientific knowledge,

6. the documents pertaining to the results of the pharmacological-toxicological tests, which are in accordance with current scientific knowledge, and the research proposal which includes information pertaining to the identity of the researcher(s), the place of the research project as well as the decision of the Ethik-Kommission, have been lodged with the appropriate authority,

7. the supervisor of the clinical trial has been informed by the scientists conducting the tests as to the foreseeable risks which arise in relation to the pharmacological-toxicological tests and their possible bearing on the clinical-toxicological tests,

7a. a research protocol exists which is of the standard of current scientific practice,

8. an insurance scheme has been set up according to subsection (3) which is invoked in the event of bodily harm or death and when no other party will pay.

A clinical trial of a new medication may only commence once it has received the approval, in pursuance to paragraph 3, of an Ethik-Kommission established at regional level; a positive approval is likely to ensue if the conditions contained in paragraph 1 are complied with. If approval is not given, a clinical trial may only commence once it has received the approval of the appropriate national authority which has 60 days to consider the proposal (according to paragraph 1 Nr. 6). The Ethik-Kommission must be informed of all unexpected difficulties or side effects which arise during the trial.

(2) Consent according to subsections 1 Nr. 2 is only effective if the person who gives it is

1. capable of forming an understanding of the nature, meaning and consequences of the clinical trial,

2. personal written consent is given. Consent can be withdrawn at any time.

¹³Arzneimittelgesetz of 19. 10. 1994 BGBl. I, 3018 at 3040. Please note that this has been translated by the author and should not be regarded as authoritative.

(3)An insurance scheme which is recognised by insurance companies must be set up according to subsection 1 Nr. 8 for all those affected. It applies to the reasonable relationship between the risks of the clinical trial and in the event of death or permanent disability to the sum of 50, 000 DM. A right to damages is negated to this extent.

(4)Subsections 1-3 apply to clinical trials involving minors as follows:

1.The medicine must be designated for illnesses affecting minors.

2.The use of the medicine as regards diagnosis or treatment of illnesses affecting minors must be reported according to medical scientific knowledge.

3.Clinical trials involving adults are unable to give sufficient test results according to current medical scientific knowledge.

4.Consent is given through a legal guardian or care assistant. It is only effective when this individual has been informed as to the nature, meaning and consequences of the clinical trial. Written consent must be given by the minor if he is capable of understanding the nature, meaning and consequences of the clinical trial.

§ 41 Specific Provisions

In clinical trials involving patients, § 40 subsections 1-3 apply accordingly;

1.The clinical trial may only be conducted once the application of the medicine under examination has been registered in accordance with medical science as being able to save the life of the patient, restore his health or alleviate his suffering.

2.The clinical trial may involve those affected by mental incapacity.

3.A clinical trial may include them [those affected by mental incapacity] providing they are able to understand the nature, meaning and consequences of the clinical trial and can make their will be known and the consent of their legal guardian or care assistant is obtained.

4.The consent of the legal guardian or care assistant is sufficient if the patient is unable to form an understanding of the nature, meaning and consequences of the clinical trial.

5.Consent of the legal guardian or care assistant is only effective if they have been informed by the doctor as to the nature, meaning and consequences of the clinical trial. Regarding retraction [of consent] § 40 (2) sentence 2 applies. The requirement for consent by a third party may be waived if the explanation as to consent is impossible.

6.Oral consent of the patient, the legal guardian or care assistant is only effective if it is obtained in the presence of a witness.

7.Explanation and consent of the patient may be waived in certain difficult cases, if it will jeopardise the success of the treatment and the will of the patient is not discernible.

APPENDIX E

RESEARCH ETHICS COMMITTEES IN SCOTLAND

RESULTS OBTAINED FROM QUESTIONNAIRES SUBMITTED IN 1994

Despite every effort made, only 12 Committees Responded Out of a Total of 21 as regards Composition and 7 Committees out of 21 as regards Practices. This small sample does nothing more than show a general tendency.

PRACTICES

VOTING PROCEDURES

- Unanimous Voting : 3
- Majority Voting : 4

MEASURES FOR MONITORING PROGRESS OF PROPOSALS

- 5 out of 7 Committees had implemented measures for monitoring the progress of research proposals

RESEARCH PROPOSALS

- Approved Without Comment : 250
- Approved After Amendment : 243
- Refused : 14

COMPOSITION

Female Members of Research Ethics Committees (See Chart One)

- Total of Committee Members : 95 of which,
- Female Members : 20 of which,
- Medical Profession : 14
- Lay Members : 6

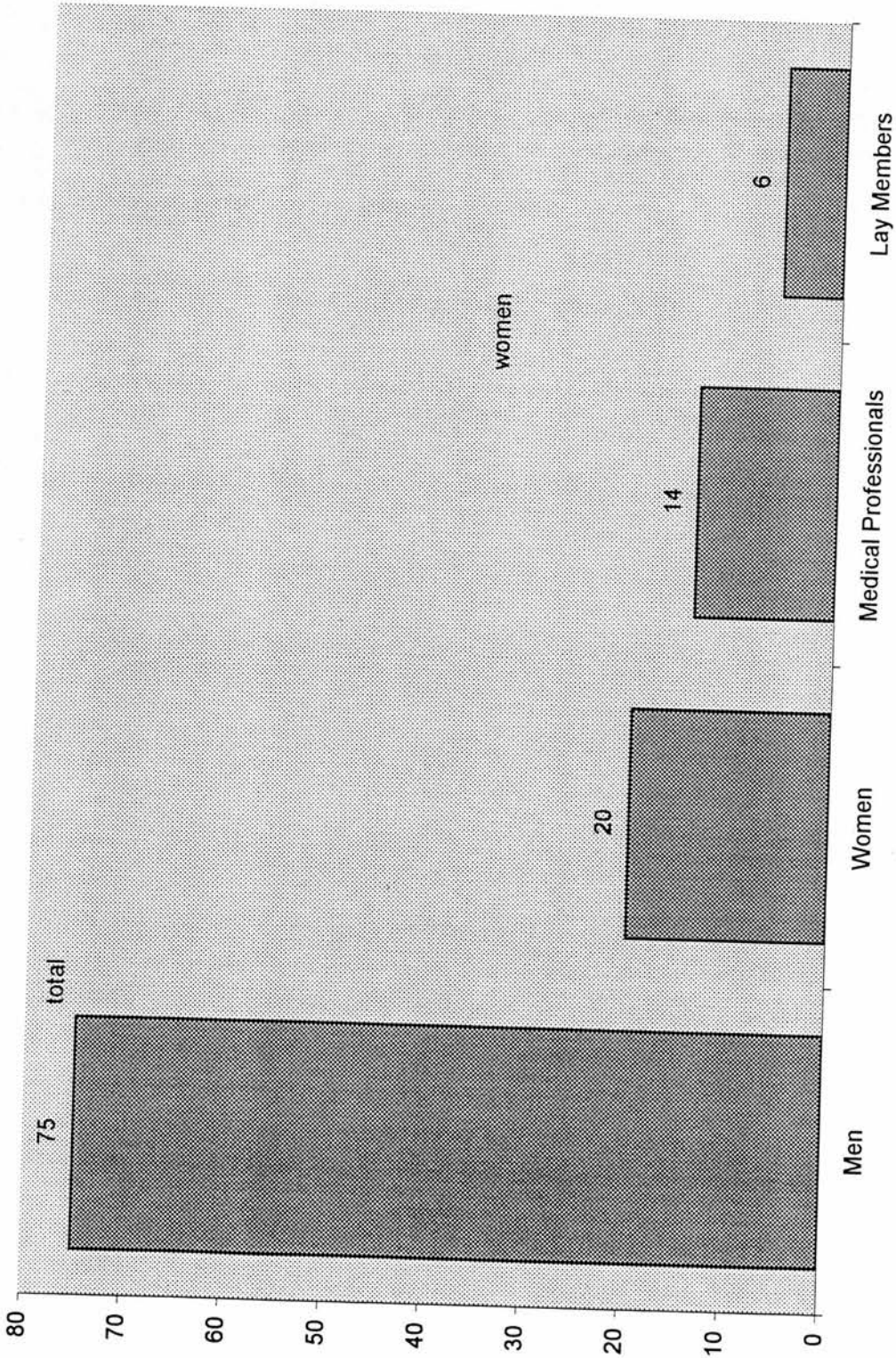
Lay Members (See Chart Two)

- Lawyers : 6
- Philosophers : 1
- Clergy : 3
- Teachers : 2
- Justices of the Peace : 4
- Local Councillors : 6
- Other : 4

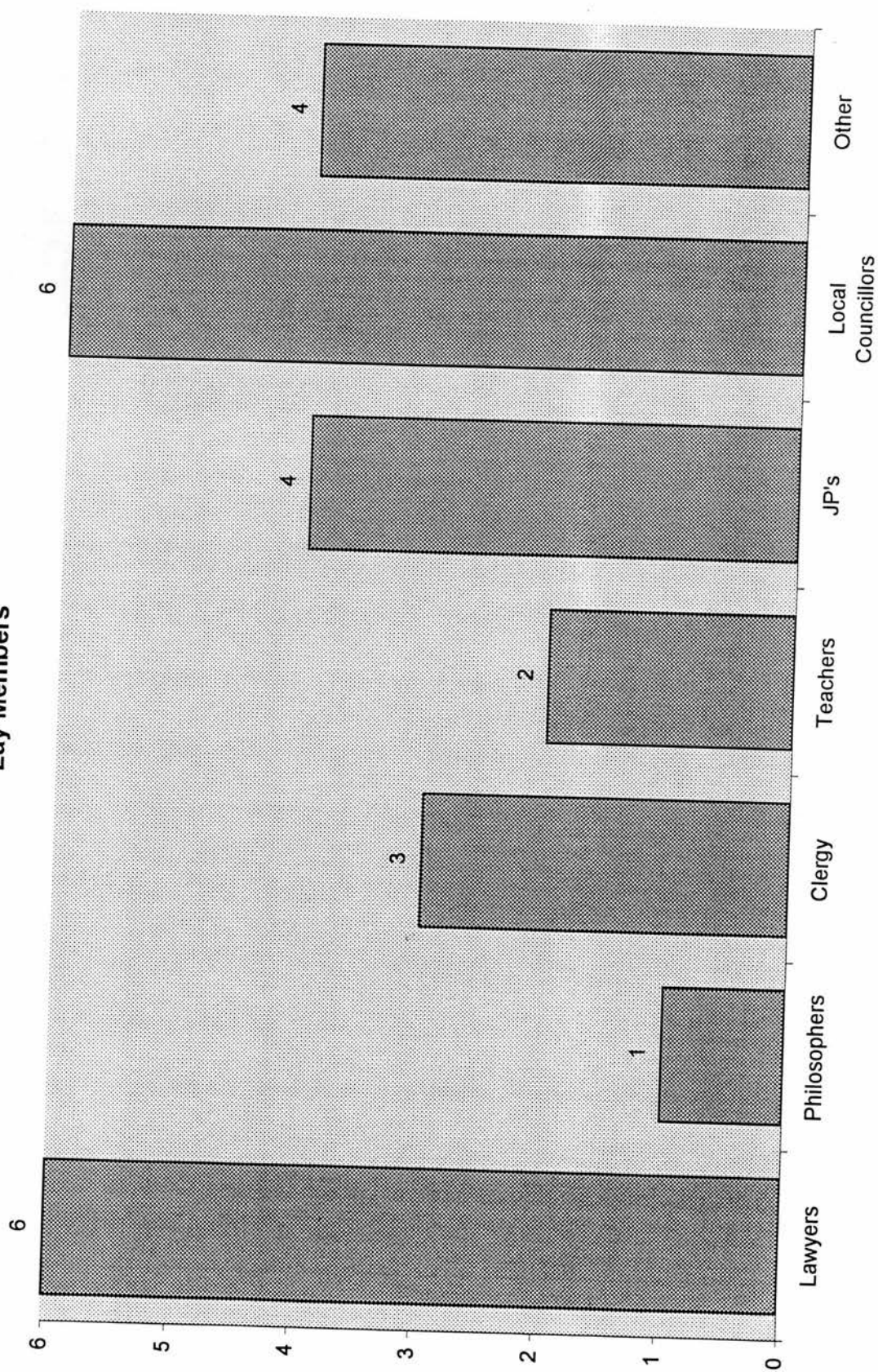
Medical Professionals (See Chart Three)

- Doctors : 74
- Paramedics (inc. nurses) : 22
- Other : 8

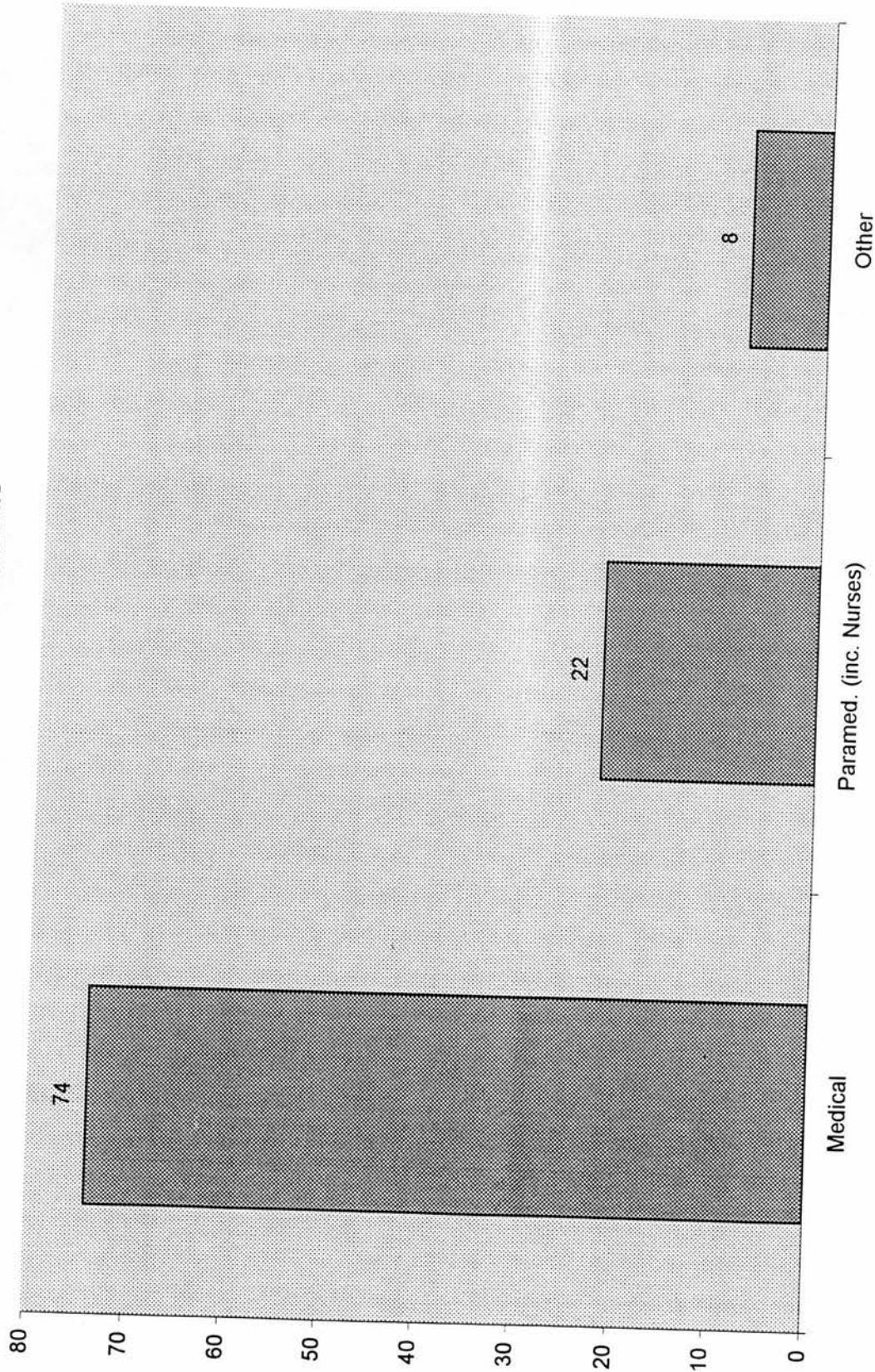
Female Members of Research Ethics Committees



Lay Members



Medical Professionals



QUESTIONNAIRE FOR RESEARCH ETHICS COMMITTEES (SAMPLE)

COMPOSITION

1. Under what authority is the committee established ?
- 1.1. How is the committee composed ? Please list the number of,

medical doctors	[]
paramedics (inc. nurses)	[]
lay members	[]
- 1.2. Please list the lay members on the committee by occupation.
- 1.3. How are the committee members chosen and what is the basis for their selection ?
- 1.4. How many women sit on the committee ? Please list the number of women who are,

medical professionals	[]
lay members	[]

MEDICAL ADVICE

2. Is there a formal provision for a medical adviser whose task it is to translate the broad nature of the proposal for research ?

PRACTICE

3. How many research protocols are dealt with,
 - 3.1. at each sitting of the committee and (on average),
 - 3.2. each year; please state whether these proposals were,

NHS	[]
Non-NHS	[]
 - 3.3. Please list the number of proposals that were,
 - (a) approved without comment,
 - (b) approved after amendment, and
 - (c) refused

3.4. How often does the committee meet each year ?

once a month	<input type="checkbox"/>
quarterly	<input type="checkbox"/>
other	<input type="checkbox"/>

3.5. Does the committee publish an Annual Report ?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

3.6. How are the decisions reached ?

majority voting	<input type="checkbox"/>
unanimity	<input type="checkbox"/>
other	<input type="checkbox"/>

3.7. Is the Proposer,

required to attend	<input type="checkbox"/>
allowed to attend the meeting ?	<input type="checkbox"/>

3.8. Once a proposal has been given the approval of the committee, is its progress monitored ?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

If the answer to this question is 'yes', please state whether this is done by the Chairman of the committee as a whole.

If the answer to this question is 'no', please state whether this is a measure which the committee would consider implementing.

3.9. If the committee refused to give its approval to a multi-centre trial, which had received the approval of other research ethics committees, would it consider bringing its uneasiness concerning the trial to the attention of a higher body e.g. the Scottish Office, the General Medical Council or the NHS management ?

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